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14. ABSTRACT MHS has fully embraced digital imaging technologies. PACS allow for the archiving and management of these images across different MTFs. It has become increasingly difficult to cope with image management requirements and challenges associated with managing network security. Two workshops were organized around each of these topics with the intent of defining the issues and determining potential solutions. The "Open Source Universal PACS Archive" workshop focused on current challenges of and open source solutions to the management of images and other clinical information in multi-center settings. The Network Security for Medical Devices and Systems workshop assessed emergent issues and operational impacts related to the imposition of non-medical Information Assurance and network security processes to the healthcare delivery domain. The following three recommendations are the output of the conference: (1) establish a medical Community of Interest (COI), (2) protect the medical COI; and (3) establish guidance for the medical device industry.					
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1.0 Introduction

The Military Healthcare System (MHS) has fully embraced digital imaging technologies. Picture Archiving and Communications Systems (PACS) allow for the archiving and management of these images across different Military Treatment Facilities (MTFs). To date, the Services have invested over \$400M procuring and deploying PACS and Teleradiology systems and have produced approximately four million procedures per year. Local MTFs are finding it increasingly difficult to cope with continued image management requirements, in terms of space and funding. They are also struggling to manage these increasingly large and complex PACS networks, in particular when it comes to dealing with network security. Two workshops have been organized around each of these topics with the intent of defining the issues and determining potential solutions. In general, the workshops were designed to bring together government, in particular from the Department of Defense (DoD), academia and industry to insure a broad view of the issues and subsequently, to recommend a comprehensive solution. Specifically, the “Open Source Universal PACS Archive” workshop focused on current challenges and potential solutions to the management of images and other clinical information in multi-center settings while the purpose of the Network Security for Medical Devices and Systems workshop was to review and assess emergent issues and operational impacts related to the imposition of non-medical Information Assurance (IA) and network security processes to the healthcare delivery domain.

2.0 Open Source Universal PACS Archive Workshop

The Open Source Universal PACS Archive Workshop was renamed as the Multi-Center Image Management (MCIM) Workshop. It was held on March 6-9, 2006 at the Renaissance Hotel and Resort in Las Vegas, Nevada. The objective of the workshop was to explore the gap of current PACS systems and future directions and discuss possible solutions with open source as a potential vehicle to achieve them as well as a Grid Computing architecture to support them. However, as the workshop progressed, it became evident that the presented challenges and solutions are relevant not just to image management but to information management in general. For two days, approximately 60 subject matter experts and practitioners from academia, government and industry met to discuss current challenges and potential open solutions to the management of information in multi-center settings. The workshop consisted of a series of presentations aimed at providing a base-line understanding of the current challenges. It also focused on open source as a potential solution with examples of robust open source projects and software methodologies. Several examples of successful business models for maintaining the development effort were described and the importance of long term sustainability beyond initial government funding was discussed. An open source approach was also introduced as a new model for collaboration between academia, industry and government.

2.1 Problem definition – what is the problem we are trying to solve?

The information requirements for a biomedical research environment are markedly different from the clinical environment. Commercial medical information and imaging systems are designed to support efficient clinical operations within a single organization whereas researchers need to be able to integrate research data with clinical data often residing in multiple distributed information repositories. The information management components for research must be able to handle more complex queries, data mining and a broad spectrum of data types beyond routine clinical data [1]. This gap between

clinical and research requirements prevents the efficient exchange, sharing, management, and analysis of multimedia medical information such as clinical information, images, and bioinformatics data as well as proteomics data sets, significantly impacting the capability to translate research into clinical outcomes. Thus, while hospitals and research communities are collecting unprecedented amounts of clinical data and research data, the ability to data mine these rich collections to support research is limited within an institution and is essentially nonexistent across institutions. Bioinformatics and proteomics data have become increasingly important in clinical research but there are not efficient ways to incorporate these data with clinical information. Multi-center clinical trials are common activities yet many of the trials are still managed manually and cannot optimize the value that a multi-center model represents. Each of these issues is a direct result of the inability to exchange multimedia clinical data and research information across different organizations and functional environments and impedes the ultimate goal of improving patient outcomes.

The current situation calls for innovative solutions that engage a broad community of users. Using an open source and open architecture framework would allow rapid implementation of scalable and robust software development in a cost effective manner by a community of users from academia, industry and government.

2.2 Possible solution – open source approach

Adopting an approach that includes open source software and an open architecture is essential to a solution that can bridge the information management gap between functional environments within an institution and across multiple institutions. An open source framework supports rapid software development while open architecture encourages interoperability across different environments. An open methodology for this effort will encourage development and implementation of software applications that can expedite translational research in a multi-center setting.

Open source software development has become a cultural as well as an economic phenomenon within the information technology (IT) community. It efficiently harnesses global skills and resources, resulting in accelerated research and development. Open source initiatives encourage high level technical communication, provide conventions for interoperable software development, establish a baseline for improvement, open the field to “beginners”, and create common ground for product development [2]. There is also a growing body of evidence that open source software produces more robust code with fewer bugs. From a government perspective, the demand for open access for taxpayer-funded projects and the need for quality and performance in mission critical applications is leading to an increased demand for open source solutions [3]. Within the National Institutes of Health (NIH) specifically, the requirements for accelerating discovery include promoting team science, lowering barriers and entry costs, enabling (enforcing) repeatable results and eliminating oversight through transparency. An open source software tactic reduces redundancy of research, enforces good research practices, and enables sharing of ideas [2]. Overall, the open source software concept has the greatest potential for success in developing tools that can bridge the clinical information management gap between the research and clinical communities.

2.2.1 Open solution in biomedical applications

There has been remarkable penetration of open source software in medical imaging research software. The Visualization Toolkit (VTK) [4] and the Insight Toolkit (ITK) [5], supported by the National Library of Medicine (NLM) of the NIH represent two large,

mature, and globally utilized open source toolkits that provide state-of-the-art imaging architectures and algorithms to application developers. VTK provides a wide range of advanced multi-dimensional visualization algorithms including volumetric reformat, volume rendering, and geometric surface rendering algorithms. ITK provides advanced image processing algorithms, with a particular emphasis on medical image segmentation and image registration algorithms. VTK and ITK were developed with a strong emphasis on advanced computing technologies and software quality. The C++ software architecture of these toolkits has evolved over the years to support a wide range of advanced algorithms and computing technologies including parallel computing. In addition, several computational tools and utilities have been developed that facilitate the global development of a high quality toolkit including a cross-platform build tool called CMake and a software quality dashboard called DART. These open source imaging toolkits, and their supporting tools and utilities, represent a large and growing resource for future open source technology solutions [6].

The Image-Guided Surgery Toolkit (IGSTK) [7], another project supported by National Institute of Biomedical Imaging and Bioengineering at the NIH, is an open source, cross platform, software toolkit. IGSTK integrates the basic components needed in surgical guidance applications and provides a common platform for fast prototyping and development of robust image-guided applications [8].

In recent years, open source software has gained visibility in the healthcare community. Several lead projects include OpenVista, a patient information system based on the Veteran Administration's system, Care2X, an integrated practice management solution in Europe and Health Infoway, a patient data-exchange venture in Canada [9].

2.3 Requirements for a successful open source software framework

While a successful open source software effort can produce rapid, innovative and cost-effective software development, making it successful requires not only an understanding of the technical and business requirements of an open source software framework but the cultivation of a community of users who can contribute and benefit from the endeavor.

2.3.1 Open architecture requirements

An open source software approach must be coupled with an open architecture to be sustainable in the long run. "Open" refers to the process used to develop standards that achieve interoperability where "architecture" defines the components, their organizations and interactions, and the design philosophy used [10]. Standardization is critical for creating interoperable, portable, and reusable components and systems; it also contributes to the development of secure, robust, and scalable systems. Grid technologies have emerged as a component of the national cyber infrastructure supporting effective healthcare information. The underlying open grid services architecture (OGSA) represents a growing trend in systems architecture. The key to the realization of this Grid vision is standardization, so that the diverse components that make up a modern computing environment can be discovered, accessed, allocated, monitored, accounted for, billed for, etc..., and in general managed as a single virtual system—even when provided by different vendors and/or operated by different organizations [11].

Grid applications in biomedical environments enable the creation and operation of distributed communities across organizational boundaries. Enhanced collaboration

environments, visualization tools, computational resources and storage capabilities are all grid services upon which Virtual Organizations can build information infrastructure. This emerging IT infrastructure enables the creation, administration and management of image based biomedical information. [12]

2.3.2 Technical requirements for an open source software framework

Open-source evangelist Eric S. Raymond suggests a model for developing open source software known as the Bazaar model. He advocates that all software should be developed using the bazaar style, described as "a great babbling bazaar of differing agendas and approaches" [13]. In order to make this model effective, Gregorio Robles suggests the following principles [14]: (1) Users should be given access to the source code of the software and be encouraged to submit additions, code fixes, bug reports, documentation etc.... Having more co-developers increases the rate at which the software evolves. (2) The first version of the software should be released as early as possible so as to increase one's chances of finding co-developers early. (3) New code should be integrated as often as possible so as to avoid the overhead of fixing a large number of bugs at the end of the project life cycle. (4) There should be at least two versions of the software - a development version with more features and a more stable version with fewer features. The development version is for users who want the immediate use of the latest features, and are willing to accept the risk of using code that is not yet thoroughly tested. The users can then act as co-developers. The stable version offers the users fewer bugs but fewer features. (5) The general structure of the software should be modular allowing for parallel development. (6) There is a need for a decision making structure, whether formal or informal, that makes strategic decisions depending on changing user requirements and other factors.

2.3.3 Distribution scheme for a successful open source software framework

As with proprietary software, open source software is distributed under a license. To help establish some degree of uniformity, the Open Source Initiative (OSI) created the Open Source Definition which is a specification of what must and must not appear in a license in order for the software to be considered open source. To meet the open source definition, a license must provide the following features [15]: (1) The license shall not restrict any party from selling or giving away the software as a component of an aggregate software distribution containing programs from several different sources. (2) The program must include source code, and must allow distribution in source code as well as compiled form. (3) The license must allow modifications and derived works, and must allow them to be distributed under the same terms as the license of the original software. (4) The license must not discriminate against any person or group of persons. (5) The license must not restrict anyone from making use of the program in a specific field of endeavor. For example, it may not restrict the program from being used in a business, or from being used for genetic research.

2.3.4 Sustainability and business models

Although an open source software framework is cost effective, it is not free. There are costs associated with the process. To maintain and grow the effort requires a sustainability plan that goes beyond the initial funding period. Money will not come in through traditional licensing fees, thus other business models need to be considered. As open source software development has matured, a number of business models for sustainability have emerged.

In the service/maintenance model companies sell support and services around the open

source software, for example, Red Hat (Linux) or Medsphere (OpenVista). In this approach, users pay for support of the software although they may choose to support the software themselves. In another approach, the vendor provides an open source code base with proprietary add-ons. Examples of this model include Sourcefire (security) and SugarCRM (customer relationship mgt). In a dual license approach, a company offers free use of its software with some limitations, or alternatively offers commercial distribution rights and a larger set of features for a fee. Both the MySQL and Sleepycat databases are examples of a dual license model. In the Aggregation Model also known as the “Lego” strategy, companies act as middlemen to assemble various open source packages into easy-to-use integrated units. SourceLabs and SpikeSource have adopted this model [9].

2.3.5 New business models for academia, industry and government

The NLM has been one of the champions of open source software development. As the imaging data from the Visible Human Project were released for public use, the NLM set out to “create a dynamic, self-sustaining, public domain and extensible toolkit that will empower researchers throughout the world to develop new segmentation and registration algorithms and create new applications that leverage the NLM’s investment in the Visible Human Male and Female data sets” [16]. The project produced the Insight Tool Kit after four years and seven million dollars of government funding. This experience made it clear to the government that while open source developed by government grants may promote open science and empower researchers, it is not free. There are costs associated with the effort such as distribution of the software, quality control of the software, and user support. In order to cross the “valley of death” between research and successful technology transfer, it is imperative that an open source effort can be converted to a financially sustaining activity.

An open source software approach offers a unique way for academia, industry, and government to work in partnership to facilitate rapid dissemination of knowledge into the commercial sector for wider applications. Software developed by the academic research community, under government sponsorship can be offered to the open source community for further testing and development and eventual adoption by the commercial industry.

The US Army Medical Research and Materiel Command (USAMRMC), Telemedicine and Advanced Research Center (TATRC) is responsible for life cycle management of over 500 medical research and development programs, with a 2005 budget of approximately \$300 million. The Center’s research responsibilities extend to execution of academic, government and industry programs in biomedical research. TATRC is currently developing a program to improve the productivity in technology transfer from research community to the commercial sector. This program uses Triple Helix strategies involving academia, industry and government to accelerate technology implementation. The open source approach is seen as a potentially effective means of making research results available for greater dissemination through timely commercialization [17].

2.4 Recommendations

At conclusion of the workshop, the participants acknowledged the technology gaps between commercial information systems that focus on efficient clinical operations within a single institution and the research environment which requires flexible access to multimedia data generated by different vendor products and residing in multiple distributed repositories. It was further noted that these gaps are not likely be addressed

by the commercial community any time soon as the market for such capability in the current biomedical environment is very limited. The participants concluded that open source, open standards, and open architecture can be efficient methods of supporting open science and improved interoperability. There was broad agreement that adequate rigor must be incorporated into an open source process in order to meet the highest standards of software quality and that long term sustainability beyond initial government funding requires strategic planning. An open source approach was also introduced as a new model for collaboration between academia, industry and government. The workshop concluded that an open source effort by the research community to develop robust, freely available tools that meet the information management needs of basic, clinical and translational research is essential to mend the gap between the research and clinical communities.

Based on the recommendations of the MCIM workshop, a new consortium has been formed to launch an open source/open architecture effort that narrows the gap between clinical and research needs by focusing on the development of software tools that enable the efficient exchange, sharing, management, and analysis of multimedia medical information. Imaging and informatics experts at Georgetown University, Washington University in St. Louis, the Northwestern University Feinberg School of Medicine and University of Geneva, Switzerland have agreed to form the Image Management Toolkit (ImTK) Consortium. Collectively this consortium represents demonstrated expertise in technology, clinical operations, technology development, and technology management within the academic, government and industrial environment.

The mission of the ImTK™ Consortium is to expedite translational biomedical research through the development of software tools that enable efficient exchanging, sharing, management, and analysis of multimedia medical information such as clinical information, images, and bioinformatics data. The ImTK™ Consortium, together with partners in academia, industry and government, will organize itself around four cores: 1) software tool development, 2) open architecture and data model implementation, 3) knowledge dissemination, and 4) management and sustainability. A well managed open source development process has been proven to produce high quality products in a cost efficient manner while simultaneously developing a collaborative user/developer community. The ImTK™ technology initiative will not only provide open source software tools and components but also an open architecture in which they may be configured and deployed. The tools will comply with existing standards such as Digital Imaging and Communications in Medicine (DICOM) and Health Level Seven (HL7) and build on the technical frameworks and workflow defined by the Integrating the Healthcare Enterprise (IHE) initiative. The open architecture will draw on the best practices of the grid computing community and service oriented architecture. This new effort will build on the expertise, processes and development tools used to create ITK and VTK. It will also bring insight and definition to the role the FDA will play in regulating open source efforts in the healthcare arena [17]. These processes will ensure the robustness of the software and extend the family of toolkits from image analysis and visualization to multimedia information management, information fusion and data mining.

Under the ImTK Consortium, three significant MCIM-related activities are in development.

1. **MCIM 2007** – On April 30 – May 3, 2007, a follow up workshop to the MCIM will be held. Funding has been requested from USAMRMC and NIBIB. The workshop will focus on open source solutions for the management of clinical and

research information in multi-center settings and will look especially to the “imaging for biomarker” community for input on requirements.

2. **Research master subject index (RMSI) using web services-based patient identification service (WS/PIDS)** – The ImTK concept is to implement an open source development process that will facilitate the rapid and robust development of information management tools that can bridge the gap between the clinical and research domain. Washington University in St. Louis and the ISIS Center of Georgetown University are collaborating to create an open source implementation of a Research Master Subject Index (RMSI) for use in Washington University’s Center for Clinical Imaging Research (CCIR). The CCIR merges state-of-the-art imaging technologies and a comprehensive IT infrastructure designed to manage clinical and translational research programs and trials in isolation from the normal clinical routine. The RMSI correlates multiple research ID domains (one per clinical trial) and one clinical ID domain to permit secure management of Protected Health Information (PHI) for research subjects participating in clinical trials and investigator-initiated research projects. It is necessary to correlate identifiers between the two domains in order to permit a researcher to access segments of a subject’s clinical electronic medical record. The project uses a patient identification service (WS/PIDS) developed at Georgetown University to support the unique research imaging environment provided by CCIR.
3. **Integration of SAML 2.0 into the IHE Cross-enterprise User Authentication (XUA) profile** – authentication/authorization issues across the enterprise are significant to the MCIM concept. Northwestern University and the ISIS Center of Georgetown University are collaborating to evaluate the use of SAML 2.0 for the IHE XUA profile.

3.0 Network Security for Medical Devices and Systems (NSM) Conference

The Network Security for Medical Devices and Systems (NSM) Conference was held June 12-14, 2006 at the Hilton Arlington Hotel in Arlington Virginia. The purpose of this conference was to review and assess emergent issues and operational impacts related to the imposition of non-medical Information Assurance (IA) and network security processes to the healthcare delivery domain. Approximately 50 participants from the Department of Defense (DoD), Veterans Administration (VA), industry and academia met for two days. On Day One invited subject matter experts representing a variety of clinical functional area and operational environments related to network management and device security, presented significant issues from their perspectives in order to establish a baseline of common understanding. On Day Two, the workshop participants were broken out into five multi-disciplinary groups and tasked with defining problems and recommending solutions to senior executive decision makers in the DoD, industry, academia, and the civilian health system for protecting these essential clinical tools and related healthcare delivery workflows. Recommendations from the five breakout groups were presented back to the plenary group, followed by further discussion intended to challenge recommended solutions and seek common ground among the conference body.

3.1 Workshop Rationale

Historically, medical devices were designed as stand-alone devices with little concern for information security (e.g., PACS). [18] However, as network infrastructures have become an integrated component of information technology (IT), many networked medical devices and systems have become essential to efficient clinical workflows in

and between hospital environments. IT and engineering staff now interconnect many IT-based hospital devices – putting large-scale enterprise systems on the same network with laboratory, monitoring, diagnostic and treatment systems. Although there are many benefits to networking medical devices, it also exposes critical hospital equipment to risk from attack by a software worm, virus, or other software security breach. Because medical devices are designed for a specific purpose with particular design considerations and constraints, it is difficult to protect them from software vulnerabilities that are typically used with other, more general purpose IT devices. Examples include routine patching of commercial operating systems in medical devices or application of anti-virus software to medical devices. Such actions can potentially change the operating function of the medical device with the possibility for negative impact on patient safety and, therefore, cannot be undertaken by the end user without the expressed support and consent of the original equipment manufacturer. Within a large enterprise, the complexity of the issue is compounded since it involves multiple healthcare devices and systems, domains and vendors. The rapid proliferation of these devices combined with increasing network security and IA requirements has resulted in an emergent need to develop a common approach to the design, deployment and maintenance of secure healthcare devices and systems in a networked environment.

3.2 Common themes – problem definition and strategic approaches

The purpose of the NSM conference was to explore the IA issues for net-centric medical devices and systems and develop a set of possible solutions with the intent of developing a recommended set of guidelines. Several common themes emerged as the subject matter experts presented particular issues and the working groups further clarified and contextualized the issues.

3.2.1 Problem definition

Although the workshop participants agreed that the common goal of network security for medical devices and systems is to protect the healthcare delivery process and that currently this goal has not been adequately achieved, the group identified five underlying issues that must be addressed in determining a suitable NSM solution.

1. Ambiguity in IA interpretation
Currently, ambiguities exist in a number of critical areas including:
 - The definition of “medical device” – thus, security requirements remain unclear
 - Application of the DITSCAP to medical devices across DoD (from base-to-base and service-to-service)
 - Lack of consistency of IA across DoD entities and the Veterans Administration
2. A standard IT approach for NSM does not exist
Multiple ad hoc approaches have been implemented as needed but there has not been a standardized approach to product development, implementation or maintenance.
3. Network control is distributed
The architecture for medical system network operations is not centralized, making effective security management impractical. The underlying architecture must provide unified management, mitigation and control.

4. Device patching/upgrading
A large number of medical devices are manufactured by various vendors and supported by a variety of operating systems, making it difficult to apply upgrades and patches. Vendors are having difficulty providing rapid, consistent remote service support due to local variability, and available bandwidth and local approval process. Additionally, there does not exist consistent guidance to allow vendors to determine and effectively communicate what software patches are necessary and unnecessary in their device portfolios. The result of these challenges is that upgrades and patches are not installed.
5. IA is not integrated into the product life cycle
Acquisition side of the life cycle needs to specify the IA requirements so that the product development side can include the requirements in the deliverable.

3.2.2 Strategic approaches for developing solutions

Developing a set of solutions to the NSM issue requires an organizational framework that can manage the various stakeholders and their different perspectives, guiding context for the issues and potential technical solutions. Several significant strategic approaches were emphasized throughout the conference.

1. Community of interest
Healthcare enterprises began connecting medical devices to networks in “mid-cycle”. HIPAA made its debut and forced the need to protect electronic individual health information systems from breaches of confidentiality, integrity without laying out a clear path of responsibility. The result has been much “finger pointing” about who should bear responsibility for repairing the vulnerabilities. It would be more effective to attack the problem as a community. By forming a Community of Interest (COI) for IA of net-connected healthcare device and systems, the stakeholders can come together to specify the requirements of the community, outline a strategy for implementation and identify concrete tasks. The COI provides the organizational framework in which to efficiently execute solutions specific to the needs of the community.

2. Medical Enclave
According to DOD directive 8500.1 E2.1.16.2 [19], “an enclave is the collection of computing environments connected by one or more internal networks under the control of a single authority and security policy, including personnel and physical security. Enclaves always assume the highest mission assurance category and security classification of the automated information system (AIS) applications or outsourced IT-based processes they support, and derive their security needs from those systems. They provide standard IA capabilities, such as boundary defense, incident detection and response, and key management, and also deliver common applications, such as office automation and electronic mail. Enclaves may be specific to an organization or a mission, and the computing environments may be organized by physical proximity or by function independent of location. Examples of enclaves include local area networks and the application they host, backbone networks, and data processing centers.”

The Army has developed their own security policies and procedures known as the Army Security Architecture for Medical (ARSAM), and the other services have similar incarnations known as the NAVSAM, AFSAM, and the VA has Medical Device Isolation Architecture Guide, all with varying success. Today an attempt is being made to consolidate these efforts into a generic medical device protected enclave security

architecture model – the goal being to present a comprehensive solution to the new MHS CIO. The North Mississippi Health System (NMHS) is piloting a test of the ARSAM for feedback in the commercial/private sector. In order to do a creditable job of creating a generic model, the solution will need to consider the Defense Information Systems Agency (DISA) Security Technical Implementation Guide (STIG).

3. Product life cycle approach

Using product life cycle as a guide would allow security requirements to match product deliverables. The FDA's vision of medical device security is grounded in the product life cycle (see Figure 1). It offers a vision that requires shared responsibility among a COI comprised of all the stakeholders. Framing network security for healthcare devices and systems in the context of the evolving product life cycle, allows the specific conditions for the acquisition, deployment and maintenance of these devices and systems in net-centric environments to ensure:

- Safety (personnel life-critical)
- Effectiveness (system and data availability)
- Security (systems and applications)
- Interoperability (systems and applications)



*Ensuring the Health of the
Public Throughout the
Total Product Life Cycle --*

Figure 1 – FDA Product Life Cycle

There exist two intersecting but distinct product life cycles. The Product Development Life Cycle is responsible for development from concept to obsolescence and involves researchers, manufacturers, regulators and vendors. The Product Acquisition Life Cycle dictates the requirements specification and decides when an acquired product will be retired. Product acquisition involves regulators, vendors, administrators, clinicians and engineers. These life cycles have tended to operate independently, resulting in some of the described security challenges. Moving toward a model in which these life cycles

interact developmentally to assure safety, enables a parallel effort to match security requirements and deliverables, particular to medical devices and systems (see Figure 2). Using the life cycle context provides a framework in which to begin specifying requirements and a pathway for graduated implementation.

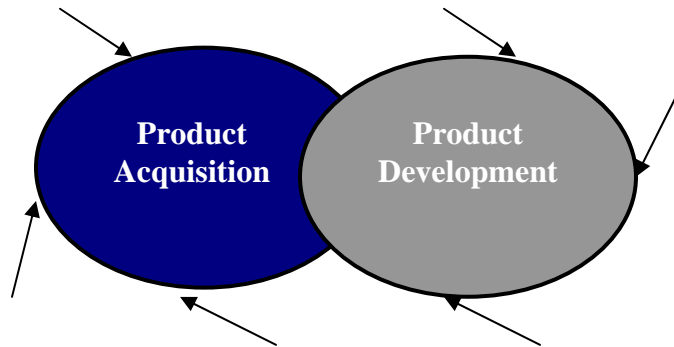


Figure 2 – The two life cycles must developmentally interact

The life cycle concept can also be used as a guide for determining how to secure immediate generation and legacy devices as well future medical devices and systems. Tables 1-3 illustrate the parallel efforts between Product Acquisition and Product development.

Future devices <i>What can be done to fully integrate network security into medical device design?</i>	
Product Acquisition	Product Development
Understand and value security as well as clinical utility and imagine all devices as networked on the enterprise	↔ Refine regulatory expectations for the networked world
Acknowledge shared responsibility for all devices on the enterprise network	↔ Identify and resolve network security issues during research and development
Adopt a context-sensitive multifaceted approach to device security	↔ Build and test prototypes with secure components

Table 1 – Application of product life cycle to future devices

Current and immediate generation devices <i>What can be done to secure the current and immediate next generation of networked medical devices?</i>	
Product Acquisition	Product Development
HIPAA	↔ HIPAA
Require technical security controls	↔ Make security a technical design criterion
Compare products on security attributes	↔ Advertise security controls
Contract for security maintenance support	↔ Include security maintenance in service packages

Table 2 – Application of product life cycle to current and immediate generation devices

Legacy devices <i>How can the exposure to legacy devices be minimized?</i>	
Product Acquisition	Product Development
Modify service contracts to include security upgrades	↔ Develop affordable, time-sensitive maintenance for reparable devices
Disconnect and retire irreparable devices from the network	↔ Identify unsupportable devices

Table 3 – Application of product life cycle to legacy devices

3.3 Working Groups

The conference participants were broken out into five multi-disciplinary groups, chaired by the subject matter experts who presented on Day One. Each group focused on NSM issues of its choosing and tasked with providing a fuller understanding of the selected issue as well as offering potential solutions.

3.3.1 Working Group 1

The participants of Working Group (WG) 1 are listed in Table 4.

Co-Chair	Jess Edwards	Chief Privacy & Security Officer	Eastman Kodak Health Group
Co-Chair	Sean Lydon	Network Security Engineer	US Army Medical Command
Co-Chair	Steven Wexler	Biomedical Engineering/Network Security	Veterans Administration
	Erich Murrell	Dep, Med Technology Integration and Support	Air Force Medical Logistics
	Richard Wetherell	Senior Director	Siemens Medical Solutions
	Frankie Rios	Information Security Architect	HCA Healthcare
	Daniel Noble	Global Support Specialist	Agfa Healthcare
	Rob Richardson	Program Manager	Army PACS Program Management Office
	Mike Fortier		NAVMEDLOGCOM
	Mark Beckner		Naval Medical Information Management Center

Table 4 – Working Group 1 Participants

WG 1 examined the ambiguities that currently exist in dealing with. WG 1 identified several ambiguities in the area of network security for medical devices and systems that need clarification or context. These are:

- What is the definition of a “medical device”? Currently, there are different interpretations. It is not clear whether medical devices are a special purpose system at the DoD or service level
- Application of DITSCAP varies across DoD (service to service and base to base)
- There is no common definition of “interconnect”

WG 1 outlined the following steps contingent on DoD making medical devices a *Special Purpose computing platform*:

- Team develops documents for all services (white paper) on a solution for having Medical Devices be a *Special purpose computing platform*.
 - Use the “medical device” definition as defined by FDA with examples of what is and what not a medical device is.
 - Define a standard interconnect as the entrance to the enclave or Vlan.
 - The Medical Enclave could be viewed as a Medical Device system by FDA
 - Develop a tailored accreditation process for medical devices
 - The interconnect is the point where DITSCAP
- Implement into DoD 8500 series so it can be implemented at all bases consistently.

3.3.2 Working Group 2

The participants of Working Group (WG) 2 are listed in Table 5.

Co-Chair	Nick Mankovich		Phillips Medical System
Co-Chair	Jeff Collmann		ISIS/GUMC
Co-Chair	John Reed		North Mississippi Medical Ctr
	Steven Lodin	Director, Product IT Security	Roche Diagnostics Corp
	Scott Bolte	Product Security Program Manager	GE Healthcare
	Steve Valentine	Project Manager	Air Force Medical Logistics
	Darrin Good	PM for IM/IT	MRMC
	Camillo Tasone		ISIS/GUMC
	Shane Coughlin	Customer Service Manager	ScriptPro
	Frank Becker		Naval Medical Information Management Center

Table 5 – Working Group 1 Participants

WG 2 chose to examine in more detail the formation of a COI whose goal is to integrate IA into the full defense acquisition life cycle of net-connected healthcare devices and systems. Using this organizational model would allow the stakeholders to come together to clarify and define the special IA requirements of the healthcare device and system community and oversee its implementation. Group 2 brainstormed the structure of the proposed COI, the tasks involved with forming the COI and reaching its goal as well as the required resources.

- Goal: Integrate IA into the full defense acquisition life cycle of net-connected healthcare devices and systems
- Objective: Define the specific conditions for the acquisition, deployment and maintenance of healthcare devices and systems in net-centric environments that ensures:
 - Safety (personnel life-critical)
 - Effectiveness (system and data availability)
 - Security (systems and applications)
 - Interoperability (systems and applications)
- Area of Responsibility:
 - Health Information Systems – AHLTA, PACS
 - Diagnostics Devices and System
 - Monitoring Devices and Systems
 - Therapeutic Devices and Systems
 - Tele-* Systems
 - Research Devices and Systems
- Membership / Stakeholders:
 - Departments
 - MHS
 - Medical Logistics
 - IA (OSD & Medical)
 - DoD CIO Office
 - VA, VHA, Indian Health

- HHS NHIN Rep
- Industry / Manufacturers
 - NEMA, Advamed, etc...
- Functions
 - Caregivers
 - Medical Systems Owners
 - Clinical Researchers
 - Ancillary medical services
 - Patient administrators
 - TMA Privacy Officer
 - Contracting
- Tasks Ahead:
 1. Sponsor acceptance of COI and COI leader appointed
 2. Identify members, convene and charter the community (Month 3)
 3. Definition of in-scope healthcare devices and systems (Month 4)
 4. Develop and deliver 8580.xx IA for Net-connected Healthcare Devices containing: (1st Draft Month 9)
 - IA requirements
 - Technical design requirements for secure connection to network infrastructure
 - Guideline for application of C&A
 - Protocols for connection and acceptance testing
 5. Publish 8580.xx IA for Net-connected Healthcare Devices (Month 12)
- Required Resources:
 - Personnel
 - Community Leader – 100%
 - Core Team Assigned personnel – 25%
 - Ad hoc Expert Support – 5-10%
 - Administrative Support – 25%
 - Monthly meetings for 12 months
 - Budget
 - Telecomm and travel
 - Administration and coordination
 - Documentation Support

3.3.3 Working Group 3

The participants of Working Group (WG) 3 are listed in Table 6.

Co-Chair	Glenda	Turner	Networks and Information Integration (NII)	Office of the Assist Sec Def
Co-Chair	Sean	Murphy		US Air Force Medical Logistics
Co-Chair	Steven	Foote	Senior Engineer	Program Executive Office
	Clarissa	Reberkenny	Supervisor Technology Specialist	TRICARE Management Activity
	Art	King		IBM (NII)
	Doug	Hunter	Quality Engineer	Siemens Medical Solutions
	Scott	Killen	Security Leader	GE Healthcare
	Carlo	Luciano	Director, Medical Technology/Networking	UPMC BioTronics
	Mike	Schomer		NAVMEDLOGCOM
	Chris	Arricale		Office of AF Surgeon General

Table 6 - Working Group 3 Participants

WG 3 looked specifically at the issue of device patching. A large number of healthcare devices and systems are manufactured by various vendors and supported by a variety of operating systems, making it difficult to apply upgrades and patches. Additionally, consistent guidance does not exist to allow vendors to determine and effectively communicate what software patches are necessary and unnecessary in their device portfolios such that critical upgrades and patches are not always installed

The group recommended the following steps:

- Patching should be categorized as follows:
 - Issues related to Patient Safety, High Visibility exploit, Probability/Frequency should be treated as 'Critical Patch' and should be patched immediately
 - Issues such as Disabled Service, Disrupt clinical operation, Workflow mitigation, External mitigation should be treated as 'Not applicable' and requires No Patches.
 - Develop criteria for categorizing as "Not applicable" that is acceptable in the DoD and commercial operating environments
 - Vendors must communicate rationale for the "Not applicable" category
 - Issues such as Low technical risk, No significant exploit, Expensive test/deploy, Minimal proliferation should be treated as 'Next Release' and can be patched later
- Develop mitigation strategy if patch is not loaded
- Industry group such as HIMMS to NEMA should sponsor and maintain a vendor vulnerability status repository
- Vendors must publish patch management point of contact, patch validation status and specific vendor guidance regarding patching policy and procedures.

The potential execution strategy for device patching is illustrated in Figure 3.

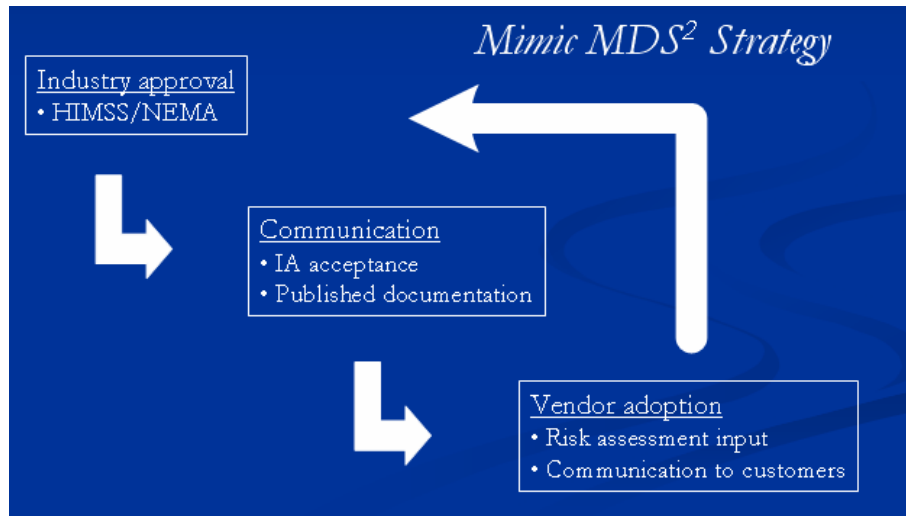


Figure 3 – Potential Execution Strategy

Another issue identified by WG 3 is lack of consistency in interpretation of IA across the DoD and VA. WG 3 proposed using the COI concept for developing consensus among the stakeholders as to which IA controls are critical. The recommendations are as follows:

- Allow “credit” for other tests
 - Proposed FDA Safety Certification
 - Defense Medical/Health IA Working Group (COI)
 - Include “Line” Communicators
 - Develop consensus among participants as to what IA controls are critical and communicate this information in procurement actions
 - Provide uniform guidance on the DITSCAP/DIACAP processes
 - Craft 85XX-IA document of language for medial devices
 - Identify/establish COI Accreditation Authority

3.3.4 Working Group 4

The participants of Working Group (WG) 4 are listed in Table 7.

Co-Chair	Brian Fitzgerald	Deputy Director	Food and Drug Administration
Co-Chair	Matt Ketko		Agha Healthcare Security Engineer
Co-Chair	Jennifer Ellet		TRICARE Management Activity
	Ed Doorn		NAVMEDLOGCOM
	John Michel	IA Task Lead	RGII Technologies Inc.
	Jason Cooper	VP & Director, Health and Life Sciences	MATRIC
	Brett Walsh	Systems Security Analyst	ScriptPro
	Keith McCall	President	KRM Associates, Inc.
	Tom Koenig		Naval Medical Information Management Center

Table 7 – Working Group 4 Participants

WG 4 discussed the lack of a standardized maintenance platform. There is no consistency in ports and protocols; the policy and procedures are not in place to enable vendor access to the devices in order to perform maintenance. Within DoD, some maintenance tool are allowed while others are not. On the vendor side, there is not a standardized set of maintenance tools.

WG 4 proposed a centralized management approach with a standardized maintenance platform. The following

- Define a medical device
- Identify as a *Special Purpose Computing Platform*
- Segregate the medical network
- Provide remote access for vendors
- Standardize IA-centric contract language
- Centralize Designated Accreditation Authority (DAA) waivers

3.3.5 Working Group 5

The participants of Working Group (WG) 5 are listed in Table 8.

Co-Chair	Phillip La Joie	Tri-Service Infrastructure Mgmt Program Office	TRICARE Management Activity
Co-Chair	Gary Crouch	Director of Telehealth	Great Plains Regional Medical Command
Co-Chair	Leroy Luginbill	STRATCOM	Joint Task Force/Global Network Operations
Co-Chair	Stephen Grimes		Vanderbilt University
	Michael Stridsberg	Product Security Architect	GE Healthcare
	Travis Gillitzer	Network & Systems Security Manager	ScriptPro
	Michael Miller	RESS/Network & Application Engineer	UPMC BioTronics
	Tom Vaccaro	Wireless Systems Engineer	Hospira, Inc.
	Doug Hunter	Quality Engineer	Siemens Medical Solutions
	Dave Lindisch		ISIS/GUMC

Table 8 – Working Group 4 Participants

WG 5 considered the need for security certification. Currently customers have no assurance that a healthcare device meets any defined level of security. A certification process would force the issue of establishing levels of security against which a product could be certified. The recommendation is to task a Standards Development Organization (SDO) (e.g., ISO, IEEE, NEMA) with the development of certification standards and levels.

WG 5 also examined the architecture for medical system network operations. Currently, control of medical system network operations is divested in hundreds of DAA's, making effective security management impractical. The underlying architecture must provide unified management, mitigation and control that includes but is not limited to the following:

- Single access point for remote service
- Common interface management (ports and protocols)

- Common security risk assessment and mitigation strategies

Group 5 recommended the formation of an MHS/ASD, Health Affairs task force that is charged with developing a strategy to transition to a single medical COI network.

3.4 Recommendations

The overarching goal is to integrate IA into the full defense acquisition life cycle of net-connected healthcare devices and systems in order to protect the healthcare delivery process. The NSM workshop produced the following recommendations:

Establish a Medical Community of Interest

Develop a Medical COI network between Army, Air Force, Navy, and Veterans Administration medical treatment entities to promote smooth and efficient transfer of medical information on a shared patient population most efficiently. Action items include:

- Separate medical healthcare delivery environments from non-medical military networks except through a limited number of interconnect gateways that must be owned by the military-DoD network/security management entity and constantly monitored, IA-compliant, and otherwise acceptable to the military and DoD for transferring unclassified but sensitive healthcare information as needed to support the medical mission across the wide area.
- Form a multi-Service and VA Task Force to define COI requirements and develop a strategy for transitioning all to a single Medical COI; - meet monthly with a target of completion within 9-12 months.
- Boundaries of the COI must also be clearly defined.

Medical COI can potentially also be used later as a model for Public Health/State health systems, civilian health systems and essential national biosurveillance activities.

Protect the Medical Community of Interest

Protect the COI and vulnerable medical devices/related systems by architecting and implementing a multi-Service (DoD) & VA defense-in-depth Medical enclave and ensure proper installation, operation, management and sustainment. The multi-Service and VA Task Force would participate in creating the enclave; however, some more technical individuals may be needed to augment the TF for this aspect. MHS is recommended as lead agent for implementation and management, with distributed operations and support by service medical IM/IT networking organizations (relationships must be defined). The action items include:

- Create 85XX-Med-IA guiding document at DoD CIO level to define medical community of interest and enclave, as well as consistent IA/certification processes and controls.
- Establish an explicit definition of medical devices/healthcare information systems that acquire, contain or transport patient medical information that is consistent with the law and functional medical environments, and IA requirements.
- Establish a standard Industry medical device patching process and include in definition of 85xxx-Med-IA controls section. An industry group such as HIMSS, NEMA, FDA, or other sponsor can maintain a vendor vulnerability status repository. Patch guidelines could mimic MDS2 strategy process involving HIMSS/NEMA governance, communication with vendors, development of IA documentation and vendor communication of status to customers. Could also model DoD process for communication of vulnerability, timely responses by

vendors to customers pertaining to applicability and authority to load patches, or deferral for a specified period of time for vendor testing and validation as necessary.

- Establish a Multi-Service/VA accreditation authority (DAA) for decisions relative to the enclave and COI network.
- Provide a common interface management framework (i.e., ports and protocols) and ensure medical products are registered for these in DoD/VA environments.
- Establish common security risk assessment and mitigation strategies.

Establish Guidance for Industry

- Establish and communicate to Industry a minimum baseline security requirement and have them assist in developing a standard Industry IA Conformance Statement that addresses these minimum requirements.
- Establish a single Protected Remote Vendor Access solution for troubleshooting and maintenance of specific medical devices/systems, to include updating IA when appropriate. Create a Security Technical Implementation Guide (STIG) for this solution and get published through DoD.
- Have a higher level of base requirements for those systems that must "touch" or interconnect directly with DoD Non-secure Internet Protocol (NIPR) networks (e.g. teleradiology/Telemedicine &/or PACS devices in deployed environments).
- Standardize contract language for medical equipment to ensure requirements for medical device IA/security baselines are included as appropriate to their use.
- Establish an independent Industry Medical Device Security certification process so that vendors may have a low-cost or no-cost way to develop/validate a product's conformance and documentation. This effort could be supported by an existing standards organization such as ISO, IEEE, NEMA.

4.0 Key Research Accomplishments

The key accomplishments are as follows:

- organization and execution of the Multi-Center Image Management Workshop
- organization and execution of the Network Security of Medical Devices and Systems Workshop

5.0 Reportable Outcomes

Manuscripts, abstracts, presentations

Mun SK, Ingeholm ML, Tohme W, Cleary K. Open Source Software for Multicenter Image Management. *Proceedings of IEEE EMBS International Conference on Information Technology Applications in Biomedicine (ITAB-ITIS 2006)*, Ioannina, Greece, October 26-28, 2006.

Tarbox LR, Vasilescu EN, Prior FW, Moore SM, Padh S, Mun SK. Research Master Subject Index – Bridging Research and Clinical ID Domains using WS/PIDS. Submitted for presentation to the Society for Imaging Informatics in Medicine, September 11, 2007 and publication in the Journal of Digital Imaging (accepted).

Funding applied for based on work supported by this award

A follow up workshop to the MCIM workshop is planned for 2007. Applications for funding have been made to the following:

- R13 to the National Institute of Biomedical Imaging and Bioengineering for conference support for \$47,000 (pending)
- Conference Support Request from USAMRMC for \$40,000 (approved)

6.0 Conclusion

Each of the workshops defined and clarified the most significant issues and offer guidance in proceeding with a solution. The MCIM workshop concluded that many of the challenges encountered in managing medical images apply to other types of multimedia medical information; thus, future endeavors should not be restricted to image management but should be expanded to include medical information management. The MCIM workshop participant also determined that an open source effort by the research community to develop robust, freely available tools that meet the information management needs of basic, clinical and translational research is essential to mend the gap between the research and clinical communities. As a result of the workshop, the ImTK Consortium has been established to support this effort. The mission of ImTK is to expedite translational biomedical research through the development of software tools that enable efficient exchange, sharing, management, and analysis of multimedia medical information such as clinical information, images, and bioinformatics data. ImTK™ will be based on an open source and open architecture approach to allow scientists, engineers and physicians throughout the world to participate in this initiative. The consortium will support the development of robust software for research applications and commercial products through conferences, training sessions, and tutorials.

The NSM workshop The overall conference strategy of the NSM workshop was for subject matter experts from a variety of clinical functional area and operational environments related to network management and device security to present significant issues of importance from their perspectives and establish a baseline of common understanding from which to then break down into multi-disciplined workshop groups to define problems and recommend solutions to senior executive decision makers in the DoD, industry, academia, and the civilian health system for protecting these essential clinical tools and related healthcare delivery workflows.

The invited experts and practitioners provided an excellent set of presentations to the conference body. They also served as co-chairs of the working groups. As co-chairs they led discussions of current challenges and stimulated definition of solutions for protecting vulnerable FDA-approved medical devices and related systems on hospital enterprise networks. It became evident that the rapid proliferation of networked medical devices and systems essential to efficient clinical workflows in and between hospital environments, combined with increasing network security and information assurance requirements has established an emergent need for the development of a common Information Technology approach to protecting the healthcare delivery process. The conference explored these issues and developed a set of possible solutions with the intent of developing a recommended set of guidelines for use by any healthcare enterprise.

Recommendations from the five breakout groups were presented back to the plenary group, followed by further discussion intended to challenge recommended solutions and seek common ground among the conference body. The following general recommendations are the resulting output of the conference.

- **Establish a Medical Community of Interest**
Develop a Medical Community of Interest (COI) network between Army, Air Force, Navy, and Veterans Administration medical treatment entities to promote smooth and efficient transfer of medical information on a shared patient population most efficiently

- **Protect the Medical COI**
Protect the COI and vulnerable medical devices/related systems by architecting and implementing a multi-Service (DoD) & VA defense-in-depth Medical enclave, ensuring proper installation, operation, management and sustainment.
- **Establish Guidance for Industry**
Establish and communicate to Industry a minimum baseline security requirement and have them assist in developing a standard Industry IA Conformance Statement that addresses these minimum requirements

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8.2 Personnel Receiving Pay

1. Robert DetreVille
2. Twarnisha Peterson
3. Adil Alaoui
4. Mary Lou Ingeholm

Appendix A

Workshop Agendas

Multi-center Image Management Workshop

Open Source Universal PACS Archive

March 6-9, 2006
Renaissance Hotel and Resorts
Las Vegas, Nevada

AGENDA

MONDAY MARCH 6

6:00-8:00pm Ice Breaker and Registration

TUESDAY MARCH 7

7:30am Continental Breakfast

Morning: The Gap: What is the Problem we are trying to solve?

- 8:00am **Welcome and Opening Remarks**
Chair: Seong K. Mun, PhD, Georgetown University
Rapporteur: Inyoung Choi, PhD, Georgetown University
- 8:15am New challenges in visualization and navigation of very large image data set
Osman Ratib, MD, PhD
Universite de Geneve
- 8:45am Image Management for Research and Clinical Trials
Fred Prior, PhD
Washington University at St Louis
- 9:15am Ongoing Challenges with Legacy PACS Data Migration within the US Army
Robert deTreville
US Army
- 9:45am *Coffee Break*
- 10:15am **Chair: Bill Mortimore, Merge Technologies**
Rapporteur: Adil Alaoui, Georgetown University
- 10:15am NLM Perspective on the Problem
Terry Yoo, PhD
NLM/NIH
- 10:45am The Digital Medical Record: Promise and Peril
Michael Pentecost, MD
Kaiser Permanente
- 11:15am User Centered Innovation Beyond Open-Source Software
Donald Harrington, MD
NIBIB/NIH
- 11:45am Market Wide PACS Implementation
Inki Mun, PhD
Aventura Hospital and Medical Center
- 12:00-1:30 Lunch**

Afternoon: Possible Solutions

- 1:30pm **Chair: Michael J. Ackerman, PhD, NLM/NIH**
Rapporteur: Lawrence Tarbox, PhD, Washington University at St Louis
- 1:30pm Filling the gaps with IHE Open Source Tools
David Channin, MD
Northwestern University
- 2:00pm The RSNA MIRC Application – An Open Source Management System for
Teaching Files and Multi-Center Clinical Trials
John Perry
Radiological Society of North America
- 2:30pm Multimedia infrastructure issues in Grid environments
Eugen Vasilescu, PhD
Georgetown University
- 3:00pm *Coffee Break*
- 3:30pm **Chair: Michael Brazaitis, MD, WRAMC**
Rapporteur: Pat Mongkolwat, PhD, Northwestern University
- 3:30pm Practical Challenges in a Heterogeneous Global PACS Architecture
Pete Killcommons, MD
MedWeb
- 4:00pm Building an Open Source Platform: A case study from Mac OS X and Apple
Ernest Prabhakar, PhD
Apple
- 4:30pm Open Source Approaches and Lessons Learned from Other Industries
Walid G. Tohme, PhD
Georgetown University

WEDNESDAY MARCH 8, 2006

Morning Session 1: The Bridge: Open Source Strategy

- 7:30am Continental Breakfast
- 8:00am **Chair: David Channin, MD, Northwestern University**
Rapporteur: Pat Mongkolwat, PhD, Northwestern University
- 8:00am Open Source Imaging Tools
Rick Avila
Kitware Inc.
- 8:30am A Case Study in Open Source Software: The Image-Guided Surgical Toolkit
Kevin Cleary, PhD
Georgetown University
- 9:00am The Open Three (O3) Consortium Project
Paolo Inchingolo, PhD
University of Trieste
- 10:00am *Coffee Break*

Morning Session 2: Industry Panel

10:30am **Chair: Fred Prior, PhD, Washington University at St Louis**
Rapporteur: Robert deTreville, US Army
(Invited Panel Participants)
Agfa
IBM
Medical Standard
Merge Technologies
Siemens
Teramedica

12:00pm *Lunch*

Afternoon Session 1: Next Steps and Government Perspectives

1:30pm **Chair: Kevin Cleary, PhD, Georgetown University**
Rapporteur: Inyoung Choi, PhD, Georgetown University

1:30pm Mind the Gap!
Michael J. Ackerman, PhD
NLM/NIH

2:00pm Triple Helix Model
Conrad Clyburn
TATRC

2:30pm Perspectives from FDA
Alford Taylor
CDRH/FDA

3:00pm The United States Measurement System: Roadmapping America's Measurement
Needs for a Stronger Innovation Infrastructure"
Richard Spivack, PhD
NIST

3:30pm *Coffee Break*

Afternoon Session 2: Innovations

4:00pm **Chair: Conrad Clyburn, TATRC**
Rapporteur: Adil Alaoui, Georgetown University

4:00pm Can peer-to-peer technology apply to medical image mgt in complex clinical
workflow?
Osman Ratib, MD, PhD
Universite de Geneve

4:30pm Application Hosting: A Standardized API for Launching and Communicating with
'Plug-in' Applications
Lawrence Tarbox, PhD
Washington University at St Louis

5:00pm HealthGrid: Grid Technologies for Biomedicine
Mary Kratz
University of Michigan

6:00-8:00pm *Reception*

THURSDAY MARCH 9, 2006

- 8:00-10:00am ***Report Back Session—All participants invited***
Chair: Walid Tohme, PhD, Georgetown University
Rapporteur Summary (10 min for each session)
Adil Alaoui, Inyoung Choi, Robert deTreville, Pat Mongolkwat, Lawrence Tarbox
- 10:00am **Closing Remarks**
Seong K. Mun, PhD, Georgetown University
- Post meeting **Golf Tournament (Optional – Sign up by COB Friday March 3rd by email**
mun@isis.georgetown.edu, green fee)

Network Security for Medical Devices & Systems Conference

Arlington Hilton Hotel
Arlington, Virginia
June 12-14, 2006

AGENDA

MONDAY June 12

6:00-8:00pm Ice Breaker and Registration
7:00-10:00pm Presenter and Conference Staff Dinner

TUESDAY June 13

7:30am Continental Breakfast

Morning-Afternoon Sessions: The Problem; - What are we trying to solve? - Potential Solutions; - What are we doing to resolve problems and mitigate Risk?

8:00am **Welcome and Introduction of Key Note Speaker:
*Seong K. Mun, PhD, Georgetown University***

8:10am **Key Note Speaker: *Mr. Carl Hendricks, (SES), CIO, Military Health System (MHS), Office of the Assistant Secretary of Defense, Health Affairs (OASD/HA)***

8:20am Morning Sessions: Presentations
Rapporteur: Adil Alaoui, Georgetown University
Chair: Robert E de Treville, Senior Advisor, PACS/EMR, MPMC/MHS

8:40am "Whose Problem is it?" Overview of the Inherent Vulnerabilities of Networked Medical Devices, and What We can do by Working Together to Protect Them; - and Minimize Operational Impacts. – It takes a Team Approach
Jeff Collmann PhD, Georgetown University

9:00am Cyber-security in Medical Devices, Problems and Related Guidance; - FDA Perspective
Brian Fitzgerald, Deputy Director, Electric Engineering and Software, FDA

9:20am Cyber-security in Medical Devices; - Industry Perspective
Jess Edwards, Eastman Kodak Health Group for
Mr. *Evan Gaddis, President and CEO, NEMA*

9:40am *Coffee Break*

10:00am Cyber-security and Medical Devices; - Changing the Manufacturer Organization
Nick Mankovich, PhD, Philips Medical Systems

10:20am Medical Device Security; - US Air Force Perspective
Sean Murphy, Major, US Air Force Medical Logistics Office

- 10:40am DoD Information Assurance Policy in Support of Bio-Medical Networks and System Security; - The Network-Centric vision. – From the medical domain, looking for feedback for improvement as a result of this conference
Glenda Turner, Office of the Assistant Secretary of Defense (Networks and Information Integration)
- 11:00am 2006 Information Assurance (IA) Workshop – Dynamic IA for the Global Information Grid (GIG): Securing the Warfighter Today and Tomorrow
Jennifer Ellett, TRICARE Management Activity (TMA), Office of the Assistant Secretary of Defense
- 11:20am Building Protected Networks for Clinical Systems; - Military Health System Perspective, Lessons Learned and Focus for the Future
Phillip LaJoie, Tri-Service Infrastructure Management Program Office (TIMPO), Military Health System (MHS)
- 11:40pm Security Assessments for Clinical Systems: - to identify vulnerabilities, analyze probability of risks, and implement safeguards; -from a real life example
Stephen Grimes, Vanderbilt University Medical Center
- 12:00pm 20 Minute Break then Working Lunch: Afternoon Presentations
Rapporteur: Adil Alaoui, Georgetown University
Chair: Jeff Collmann, PhD, Georgetown University
- 12:20pm Army Security Architecture for Medical (ARSAM)
Steven Foote, Senior Engineer, Program Executive Office, Enterprise Information Systems Technology Applications Office
- 12:40pm Army Medical Command's Defense in Depth (DiD) Architecture; -history, goals and recommendations
Sean Lydon, US Army Medical Command Defense in Depth Engineer
- 1:00pm Proxy Servers and Secure Communications for Clinical Workflows
Matt Ketko, Agfa Healthcare Security Engineer
- 1:20pm Lessons Learned from Implementation of the ARSAM in a Private Healthcare Enterprise
John Reed, North Mississippi Medical Center/Health Services
- 1:40pm Veterans Administration (VA) Medical Network Isolation Architecture
Steven Wexler, Veterans Administration
- 2:00pm *Coffee Break*
- 2:20pm Security Architecture for Radiology Picture Archive and Communications System (PACS) in the Great Plains Regional Medical Command (GPRMC)
Gary Crouch, Director of Telehealth, GPRMC
- 2:40pm Overview of Global Interconnectivity of the Healthcare Community, the Internet, and DoD Infrastructure
LeRoy Luginbill, Strategic Command, Joint Task Force – Global Network Operations
- 3:00pm Late Afternoon Session – Initial Break-out into Groups
Coordinators:
Jeff Collmann, PhD, Georgetown University
Neal Neuberger, Health Tech Strategies

3:30pm *Breakout Group Session*

6:00pm *Adjourn for Day*

7:00pm *Dinner*

WEDNESDAY June 14

7:30am *Continental Breakfast*

8:00am *Morning Session: "Break-out Groups"*

12:00pm *20 Minute Break, then working Lunch: "Break-out Group Presentations"*

12:20pm Afternoon Session: "Break-out Group Presentations"
Rapporteur: Neal Neuberger, Health Tech Strategies
Rapporteur: AdilAlaoui, ISIS, Georgetown University
Chair: Robert E. de Treville, Senior Advisor, PACS/EMR, MPMC/MHS
Chair: Jeff Collmann, PhD, Georgetown University
Chair: Seong Ki Mun, PhD, Georgetown University

3:00pm Co-Chair Panel Summary Discussion: "Consolidate recommendations and define next steps"
Rapporteur: Neal Neuberger, Health Tech Strategies
Rapporteur: AdilAlaoui, ISIS, Georgetown University
Chair: Robert E. de Treville, Senior Advisor, PACS/EMR, MPMC/MHS
Chair: Jeff Collmann, PhD, Georgetown University
Chair: Seong Ki Mun, PhD, Georgetown University

4:30pm Conference Survey

5:00pm Conference Adjourns

Appendix B

Workshop Abstracts

Multi-center Image Management Workshop

Open Source Universal PACS Archive

Abstracts

New Challenges in Visualization and Navigation of Very Large Image Data Set

Osman Ratib, MD, PhD, Universite de Geneve

Display and interpretation of multi dimensional data obtained from the combination of 3D data acquired from different modalities (such as PET-CT) require complex software tools allowing the user to navigate and modify the different image parameters. With faster scanners it is now possible to acquire dynamic images of a beating heart or the transit of a contrast agent adding a fifth dimension to the data. Clinicians and referring physicians have often only limited access to medical images through a web-based system with slow access and relatively limited image manipulation capabilities. With the recent evolution of imaging modalities toward high resolution multidimensional imaging techniques users have started to rely on advanced image display and navigation features such as image fusion, 3D volume rendering and multiplanar reformatting. These features are becoming essential for physicians and surgeons that depend on adequate visualization of the image data to perform complex interventions or assess the effect of a given therapeutic procedure

Osirix is an Open Source advanced visualization software and provides real time navigation in very large sets of 5 dimensional data based on an intuitive and user friendly user interface. This project is focused on the user interface and means for interactively navigating in these large data sets while easily and rapidly changing multiple parameters such as image position, contrast, intensity, blending of colors, magnification etc. It was specifically designed for non-experts users and clinicians for convenient and efficient image visualization and interactive navigation through complex sets of data.

Issues

- *Exponential increase in image data of Multidetector CT, Multimodality imaging (PET-CT), Functional imaging, Time-varying image data and Molecular imaging.*
- *Imaging modalities are evolving toward high resolution multidimensional imaging techniques from 3^d dimension CT, MRI, PET into 5th dimension dynamic fusion image*
- *Image display and navigation features are becoming essential to perform complex interventions or assess the effect of a given therapeutic procedure*

Challenges

- *Osirix is a Open Source advanced visualization software and provides real time navigation for 5 dimensional image data*
- *Distributed under the GNU-General Public License. Anyone can have access and modify the source code.*
- *Clinicians and referring physicians can have better access to medical images and better visualization capabilities*

Next steps

- *Currently based on peer-to-peer data sharing technology. Can it be applied for complex clinical workflow?*

Image Management for Research and Clinical Trials

Fred Prior, PhD, Washington University at St. Louis

Clinical PACS were not designed to readily support the image management and analysis needs of multi-center clinical trials and other research imaging applications. Similarly, PACS image repositories have been optimized to support diagnostic radiology workflow and do not support the integration of multi-scale information or complex information retrieval requests needed to support data mining based research. This talk reviewed their laboratory's experiences with image based multi-center clinical trials, the creation of research image libraries and management systems for a research imaging center to establish requirements for future open source distributed image and information management tools.

Issues

- *Requirements for research applications are quite different from the standard clinical environment. Research images are either drawn from clinical records or are specifically collected – in both cases they are stored in the clinical PACS.*
- *Dual use of the clinical PACS can complicate clinical workflow if the research study is outside the normal standard of care or the research protocol requires a different workflow model.*
- *Clinical PACS are designed to manage PHI and have limited ability to support de-identification or anonymization*
- *PACS image repositories do not support the integration of multi-scale information or complex information retrieval requests needed for data mining or outcomes research.*
- *The research community needs well designed, freely available tools that meet the information management needs of the full spectrum of basic, clinical and translational research*

Challenges

- *The Silent Infarct Transfusion Trial (SITT) is a multi-center clinical trial to determine the efficacy of blood transfusion therapy as a treatment for preventing silent strokes in children with sickle cell disease. The imaging core of a multi-center trial provides a number of services such as image accumulation, de-identification, image transport, quality assurance, image management, image processing or presentation for reading, workflow management and collection and analysis of imaging results*
- *CLINDB/ClinPortal is collaborative project just getting underway. It provides translational researchers access to information gathered as a result of routine patient care and integrated access to data acquired from research subjects (and animal models) and stored in multiple information repositories.*

Next steps

- *Information management components must deal with a broad spectrum of data types and support complex queries and data mining*

Ongoing Challenges with Legacy PACS Data Migration within the US Army

Robert E. DeTreville, US Army

The US Army has been acquiring and archiving PACS images since 1992. Migration of legacy PACS images has taken years to figure out and still is not yet complete within the US Army. Even data migration from older to newer systems with the same vendor is problematic, much less between legacy and incumbent vendors. This talk generally describes some of the problems and issues associated with the current data migration process, and addresses some areas of focus for future improvement.

Issues

- *US Army has been acquiring and archiving PACS images since 1992. Initial effort focused on migrating Legacy Data to new archive systems as PACS systems are upgraded or replaced.*
- *Integrating and managing all enterprise clinical information into the multi-media Electronic Medical Record (EMR) is becoming new focus*
- *A standard vendor-independent approach to image archive and management would simplify the challenges of data migration in the future.*
- *Migration process is more difficult when multiple PACS vendors are involved, e.g. the legacy PACS vendor that no longer has the customer's PACS business and the new vendor.*

Challenges

- *Past migration experiences of Brooke Army Medical Center (BAMC), Madigan Army Medical Center (MAMC), and Tripler Army Medical Center (TAMC) are generally "Not Good", but getting somewhat better*
 - *Different image storage format*
 - *Different image compression ratio*
 - *Corrupt information on the platter*
 - *Low vendor support*

Next steps

- *We need a more standard approach to storing, protecting and managing patient image data; such that the long term PACS archiving and management process is independent of proprietary vendor protocols, lengthy data migration activities, and related contractual challenges.*
- *Medical images must be protected, preserved, and readily available throughout the continuum of care.*

MCIM Research Workbench: Committed to Science and Accelerating Development

Terry Yoo, PhD, NLM/NIH

Issues

- Multi-center image management is comparative exploration, reduces redundancy of research, enforce good research practices, and share ideas
- Requirements for accelerating discovery include team science, lowering barriers and entry costs, enabling (enforcing) repeatable results and eliminating oversight through transparency
- Academia improves communication, participation, reproducible science and can't sequester results (ex, GenBank)
- Industry accelerates technology transfer, expedites incorporation of new research, eases staffing and employment, does not compete with product development and can't gain exclusive rights to algorithms (ex, Osirix)
- Government improve accountability, reduce redundancy, and increases impact of funding
- Open source initiatives encourage high-level technical communication, provide conventions for inter-operable software development, establish a baseline for improvement, opens the field to "beginners", and creates common ground for product development
- NLM committed to open source/ open data for the last 10 years and funded the ITK \$12 million over 5 years. It is the time: We have commodity network and commodity computing there is opportunity for scientific discovery and shared engineering
- MCIM research workbench is beyond clinical trials, beyond software development, beyond inexpensive PACS. It is "Grand unification" across scale and domain.
- Business Model Consortium : Not too small community, start with a medium community and grow to an international movement

Challenges

- Make policy changes emphasizing visualization
- Long term recommendation
- Create collaborative programs
- Investment in the future
- National investment, and open source software and open data collections

Next steps

- Extreme programming and daily testing is the key for success
 - Testing anchors and drives the development process (Dart)
 - Opens up the development process to everyone
 - Developers monitor the testing dashboard constantly
 - Problems are identified and fixed immediately
 - Developers receive e-mail if they "break the build"

The Digital Medical Record: Promise and Peril

Michael J. Pentecost, MD , Kaiser Permanente

The advent of the electronic medical record (EMR) improves patient safety and prevents clerical mistakes as well as miscommunication between radiologists and physicians. Also, integration of EMR data from multiple medical practices facilitates surveillance for potential epidemiological threat. EMRs are expected to streamline business practices through simplified medical record access, improved workflow, enhanced coding and charge capture, faster claims submission and limited redundancy. In spite these benefits, some challenges have impeded the dissemination of EMRs such as lack of standards and inconsistent integration with clinical workflow coupled with concerns about privacy and cultural acceptance. In order to achieve seamless integration of clinical and radiology information within and across the hospital, the existing standard such as HL7, DICOM and SNOMED should be fully integrated, especially at the level of small practices. (Source: Journal of the American College of Radiology).

Issues

- *The integrated electronic medical record (EMR) improves patient safety and prevents clerical mistakes as well as miscommunication between radiologists and physicians.*

Challenges

- *Health Connect is Epic version of Kaiser Permanente electronic medical record. It improves:*
 - *Integration: single, comprehensive medical record with provisions of information including past visits, lab results, radiology reports, immunization records, medications and allergies.*
 - *Clinician access: 24/7 complete access to patient information*
 - *Patient access: on-line access to medical records and service such as email physicians, prescriptions refill, lab results review, health information research, and appointment scheduling*
 - *Efficiency: physicians can provide medication, order lab work, radiology and provide referrals from single system at point-of-service and eliminate redundant entry and it improves advanced care planning (simple registries, reminder systems, protocols, etc.)*
 - *Safety: system alerts support patient care by catching abnormal results, negative trends, patient history, chronic problems, and drug/procedure combinations*

Next steps

- *A program-wide system that integrate the clinical record with appointments, registration and billing will enhance the quality of patient care*
- *In order to achieve seamless integration of clinical and radiology information within and across the hospital, the existing standard such as HL7, DICOM and SNOMED should be fully integrated, especially at the level of small practices.*

User Centered Innovation beyond Open-Source Software

Donald P. Harrington, MD, MA, NIBIB/NIH

The open source movement is evolving from a software development process to cultural phenomenon. Within the NIH and other government agencies, the demand for open access for taxpayer funded projects and the need for quality and performance in mission critical applications is leading to an increased demand for open source solutions. While the primary focus of the NIH is research, an important component of the institute's mission is translational research for clinical applications. A variety of software developed for research purposes is translatable to clinical applications and there is no better place to start than in clinical imaging. While open source software is a key factor, another critical aspect of the equation is user-centered development. Therefore, a solution to the multi-institutional image management dilemma is a combination of both aspects. This presentation focuses on open source and the critical needs of the end user. While the issues of intellectual property rights and business model are important to the overall success of the open source movement, it is peripheral to the end user. The end user needs innovation, flexibility, quality and performance. Important critical issues include funding sources, governance, leadership and sustainability.

Issues

- *There is clearly a need to consolidate and scale up various open source research efforts and develop an open clinical imaging system to support MCI needs with end user focus*
- *Open source movement is progressing from software development to cultural phenomenon*
- *The end product is much better when developer and end user are the same*
- *There are currently sustainable business models using OSS*
- *The government is using OSS even in mission critical applications*

Key factors

- *Controlled and verifiable process for software development*
- *Identifiable entity that certifies process and will audit and follow up on post marketing issues*

Next steps

- *Intellectual property rights is remaining as a controversial issue*
- *Liability issues are unclear*
- *FDA approval of OSS is no different than proprietary software*
- *Current solutions are not suitable for existing average user*
- *Unanswered questions include:*
 - *Can the existing process scale to clinical imaging?*
 - *Which organization or consortia of organizations can provide governance?*
 - *Who will pay for the process?*
 - *Differing business models concerning open source*
 - *What is the government/NIH position on the subject and why does it matter?*
 - *What is an open source community and why do they work?*

Market-Wide PACS

In K. Mun, PhD, Aventura Hospital and Medical Center

The strategy of PACS implementation has gone through several revisions recently. It started it out as a radiology centric system to be managed by radiology department. Due to the complexity of network and storage issues as well as interface required to HIS, IS/IT department support was essential for a successful PACS project. However, due to the success of multi-slice CT scanners, high performance MRI scanners, digital X-ray and digital cath labs, we have seen huge increase in data volume forcing volumetric image viewing as well as demand for enterprise-wide image distribution. With the cost of communication dropping along with shortage of radiologists, we are now witnessing next evolution of implementing multi-hospital PACS, or market-wide / regionalized PACS. This presentation will focus on the new trend in market-wide PACS implementation and what are the potential impacts on radiology as well as hospital management.

Issues

- *Current PACS issues are emerging new devices such as 64 slice CT, Digital Cath Lab, Digital Mammo, standardization between DICOM and HL7, integration between radiology, cardiology, PDA and RFID, patient safety, evidence based medicine, performance based payment and Regional Healthcare Information Organization*
- *Management issues such as selecting vendor, installation, maintenance & up-grade, support*
- *Clinical issues figuring out core requirements, conflict between radiologists & cardiologists and ER & OR*
- *Budgeting issues regarding how to set a budget*
- *CEO issues like competitive tool and liability*

Challenges

- *Market-based PACS can reduce cost by sharing resources, provide easier to manage mobile patients and better coverage by specialists, optimize radiology resources, improve patient safety, and lower communication cost.*
- *Market-based PACS models include one large centralized database with a governing body, assemble distributed data with API functionalities, and share distributed data under peer-to-peer federated architecture*

Next steps

- *Resolving outstanding question such as:*
 - *Sustainability*
 - *Who is in charge*
 - *Organization (IT structure)*
 - *Scalability*

Filling the Gaps with Open Source IHE Tools

David S. Channin, MD, Northwestern University

This presentation is an overview of the typical clinical and research imaging environment. Gaps in meeting clinical and research needs, identified in other presentations, are highlighted. The Integrating the Healthcare Enterprise initiative is introduced and the IHE model for radiology operations explained. A model for filling the identified gaps using open source IHE actors is presented.

Issues

- *No single vendor can meet all needs, difficult to deploy best-of-breed*
- *Complex processes involving heterogeneous systems*
- *Standards are necessary but not sufficient*
- *Data trapped in proprietary silos*
- *Commercial systems are **not** tools, tools can be used for purposes that the creator did not envision*
- *Commercial systems do not innovate or iterate rapidly, focus on mundane requirements of the early and late majority*

Challenges

- *IHE defines use cases and workflows*
 - *Local site workflows: knowledge from “The Lab” workflow feeds “The Clinical” workflow*
 - *Gather sites into federated regional operations (RHIOs)*
 - *Gather RHIOs into federated national networks (NHIN), perhaps coordinated by national agencies (NLM?)*
- *IHE helps fill the gap in innovation by choreographing transactions between actors via standard protocols to address real world use cases. This includes interoperability between clinics, and RHIOs*

Next steps

- *There are many IHE actors that are not yet available, in particular the reporting workflow – let’s build them using Open Source methodologies?*
 - *Sniff all DICOM and HL7 interactions, to create replicated DBs*
 - *Use Protégé ontology engine to recognize transactions*
 - *Use the transactions to drive IHE workflow engine, including reporting*
 - *This could be used to both drive clinical as well as research workflow, and allows the introduction of new tools*
 - *Incorporate feedback, for quality improvement, from other med specialties (e.g. pathology)*

The RSNA MIRC Application – An Open Source Management System for Teaching Files and Multi-Center Clinical Trials

John Perry, Radiological Society of North America

Medical Imaging Resource Center (MIRC) is an open source initiative of the RSNA to provide tools to radiology in support of teaching files and clinical trials. MIRC is implemented as a peer-to-peer system that facilitates the sharing of information in a community of systems world wide. This paper describes the architecture of the MIRC system and details its use in multi-center clinical trials, including lessons learned with respect to:

- Architectural concerns in multi-center trials: the topology of a multi-center trial*
- Software installation at imaging centers: the remote IT problem*
- Software configuration: managing software and configuration updates*
- Anonymization and pseudonymization: central vs. distributed remapping*
- Data formats: beyond DICOM*

Issues

- *RSNA's MIRC objectives are global sharing of digital teaching files, scientific, technical, and educational materials and research datasets of original format images*
- *Lessons from field centers include*
 - IT support is almost unavailable.*
 - Initial software installation requires a human being, but it should be simple.*
 - Software updates should require a person to trigger them.*
 - Anonymizer scripts should be automatically updated.*

Challenges

- *MIRC provides global sharing of data, educational materials, etc.*
 - Cooperating libraries with a common query mechanism*
 - MIRC specifies how to find and access documents*
 - There are 8 independent implementations of MIRC, including the RSNA implementation*
- *MIRC provides data collection for clinical trials*
 - Collect data with PHI on site with Field Center*
 - Optionally anonymize and send to central MIRC site*
 - MIRC site then distributes data via DICOM and/or an external DB connection*
 - Complications:*
 - o Trial subject registration/mapping to patient ID*
 - o Multiple PIs*
 - o Separate PIs for imaging and overall trial*
 - o Transfer of non-image objects*
 - o Separate analysis sites (not PIs) that retrieve data, and return results*
- *Can MIRC tie into IHE?*

Multimedia Infrastructure Issues in Grid Environments

Eugen Vasilescu, PhD , Georgetown University

Large databases of (clinical) images are being created and the need to share information is accepted by all healthcare stakeholders, including practitioners, patients, vendors and researchers. Sharing information through point-to-point interfaces is a known dead-end. There is a need to effectively bridge the potential image islands in a standardized manner and Grid Environments offer the promise of standardized flexible support in (multimedia) distributed environments.

Issues

- Clinical images are getting larger and needs to share information across all healthcare stakeholders including practitioners, vendors and researchers are growing
- Need to integrate the distributed images in a standardized manner

Challenges

- *Grid offers flexible support of distributed environments*
- *Handle binary data as an attachment above a certain size threshold*
 - *By reference as URI*
 - *By value by SOAP (SwA) or WS attachments*
- *In relation to IHE, GRID need the right granularity of*
 - *what to move around*
 - *what is a good logical view*
 - *the use cases that are multi-center*
- *Chatty exchange of messages is not very good for GRID, so IHE and related protocols may need adjusting*

Next steps

- *Need to define scope of multi-center collaboration, what is the nature of the virtual organization? Do we need to create them on the fly?*
- *Grid provides a standardized way of dealing with state (in WSRF in GT4), but what is its role in MCIM?*
 - *Notification of state changed*
 - *State maintenance over days instead of minutes*
 - *Backup/Recover*
 - *Link unavailability*
- *Lots of issues, but there is a 'critical mass' of tools available to tackle MCIM.*

Practical Challenges in a Heterogeneous Global PACS Architecture

Peter Killcommons, MD, MedWeb

MedWeb has had the opportunity to develop architecture to manage the imaging workflow across a global organization. This presentation provides insight into the impact of firewalls, intrusion detection systems, and multi-domain security issues from an IT perspective, acceptable user interface performance from a clinical practitioner's perspective, and real world accounting of the frequency and types of problems typically encountered in this environment. These include political, technical, and architectural problems as well as some suggested solutions.

Issues

- *Integration and deployment of heterogeneous PACS*
 - *High turnover rate of personnel*
 - *Variety of computing backgrounds*
 - *Require rigorous training on new replacement*
 - *Require good installation and operational manuals*
- *Heterogeneous issues*
 - *Mobile PACS with satellite*
 - *Networking (including security, encryption)*
 - *IT integration with other vendors*
 - *5-6 connectivity*
 - *Shared unread worklist*
 - *Conformance statements vs. real implementation*
 - *Administration (network, user training, s/w, h/w)*
 - *Clinical expectation*
 - *Multi-vendors cooperation*
 - *Configuration management*
 - *Deployment*
 - *Using open source to build PACS*

Building an Open Source Platform: A Case Study from Mac OS X and Apple

Ernest Prabhakar, PhD, Apple

This presentation describes how Open Source and Open Standard technologies have helped make Mac OS X the world's most advanced operating system, and Apple the world's largest vendor of open source software. He discusses the advantages and challenges of building a platform using open source, and describe key Apple technologies of relevance to the PACS community.

Open Source Imaging Tools

Rick Avila, Kitware, Inc.

Healthcare researchers and commercial solution providers are increasingly utilizing open source toolkits to develop advanced clinical imaging solutions. The Visualization Toolkit (VTK) and the Insight Toolkit (ITK) represent two large, mature, and globally utilized toolkits that provide state-of-the-art imaging architectures and algorithms to application developers. VTK provides a wide range of advanced multi-dimensional visualization algorithms including volumetric reformat, volume rendering, and geometric surface rendering algorithms. ITK provides advanced image processing algorithms, with a particular emphasis on medical image segmentation and image registration algorithms. VTK and ITK were developed with a strong emphasis on advanced computing technologies and software quality. The C++ software architecture of these toolkits has evolved over the years to support a wide range of advanced algorithms and computing technologies including parallel computing. In addition, several computational tools and utilities have been developed that facilitate the global development of a high quality toolkit including a cross-platform build tool called CMake and a software quality dashboard called DART. These open source imaging toolkits, and their supporting tools and utilities, represent a large and growing resource for future open source technology solutions.

Open Source Approaches and Lessons Learned from Other Industries

Walid G. Tohme, PhD, Georgetown University

Open Source software is becoming more widespread and open source business models have emerged that seem to be successful. They include a service approach, a licensing strategy, the aggregator model, a proprietary add-on approach and finally hardware built with open source software. This presentation explores these models with case studies to illustrate them. It remains to be seen which of these models or which combination would be appropriate for multi-center image management but it is clear that Open Source will play a key part in the future. Challenges to adoption and success of Open Source are also discussed.

Issues

- *What is Open Source? Does it yield more benefits or incur fewer costs than other options?*
- *What makes OS timely now?*
- *What OS business models exist?*
- *How are the traditional players reacting?*
- *What challenges still exist?*
- *Which model(s) are appropriate for MCIM?*

Challenges

- *Open source is likely to become the dominant model for creating software to improve the quality of care in a cost-effective way*
- *Open Source is not the end of commercial healthcare software suppliers nor is it free software for all. However, it will provide a reference point and an agent for managing price*
- *Successful open source requires*
 - *Well-written document*
 - *No hidden functionalities*
 - *Full access to source code*
- *Open source license*
 - *Unrestricted (Apache, BSD)*
 - *Restricted (GPL, LGPL)*
- *Emerging open source models*
 - *Service and maintenance fees*
 - *Proprietary add-on*
 - *Dual licensing (GPL vs. commercial)*
 - *Aggregation of several open source projects*
 - *Embedded (Linux on Tivo)*

Next steps

- *What final model will be adopted remains to be seen. The key is to find the winning framework for industry, academia and government.*

A Case Study in Open Source Software: The Image-Guided Surgical Toolkit

Kevin Cleary, PhD, Georgetown University

Open source software has tremendous potential for improving the productivity of research labs and enabling the development of new medical applications.

The Image-Guided Surgery Toolkit (IGSTK) is an open source, cross platform, software toolkit. IGSTK integrates the basic components needed in surgical guidance applications and provides a common platform for fast prototyping and development of robust image-guided applications. This presentation will give an overview of the IGSTK framework and current status of development including an example needle biopsy application. We will also discuss the state machine architecture and the software development "best practices" used in the project. This project has been a collaborative effort between Georgetown University, Kitware Inc., Atamai Inc., and Arizona State University. The work is supported by the National Institute of Biomedical Imaging and Bioengineering at the National Institutes of Health.

Issues

- *Software is a critical component for image-guided surgery; however software development takes the most time in these systems.*
- *It is difficult to develop robust software*
- *Medical researchers are not necessarily software professionals*

Challenges

- *Image-guided Software Toolkit (IGSTK) aims to provide common functionality for image-guided surgery applications*
- *Initial release at SPIE Medical Imaging Conference in February 2006 (http://public.kitware.com/IGSTKWIKI/index.php/Main_Page)*
- *A robust software development for IGSTK*
- *BSD license, features of 2D/3D visualization, several image registrations, GUI, error capturing, logging, APIs*
- *Project measurement*
 - *Competent people*
 - *Constant communication*
 - *Producing iterative release*
 - *Managing source code from a quality perspective*
 - *100% code testing coverage*
 - *Building and testing*
 - *Software process with robust tools*
 - *Focusing on current requirements*

The Open Three (O3) Consortium Project

Paolo Inchingolo, PhD, University of Trieste

Born from the fusion and the integration of the DPACS project (1995) of the University of Trieste and the Raynux /MARiS project (2002) of the University of Padova, the Open Three Consortium (O3) is an innovative Project of these two Universities, in the frame of international networks ABIC-BME and ALADIN and of the about 50 bilateral cooperation Agreements of the Higher Education in Clinical Engineering (HECE), University of Trieste, with Healthcare and Industrial Enterprises as well with Governmental Agencies. These Agreements are the bases of the O3 Consortium Community of Users, which counts, up today, O3 installations in five Italian Regions and running installations in many other countries.

The goals of O3 are archiving, transmission, exchange, retrieval and visualization of data, signals, images and reports, within an integrated hospital-territory-citizen system. All O3 systems can be scaled at any range, up to national and international dimensions. O3 is developed completely as Open Source and with Java technology, to facilitate its re-use and portability, fostering a wide diffusion in Italy and abroad.

It is fully data-base, OS, HW and language independent, and 100% compliant with the world-wide interoperability initiative "Integrating the Healthcare Enterprise" (IHE).

O3's "bricks" are built according to IHE "Actors". O3's information flows are totally compliant with IHE Integration Profiles. Currently, O3 offers 19 IHE actors and 15 IHE profiles, totalling 53 actors/profiles couples.

The O3 Enterprise, a spin-off from the two Universities, it now being constituted, to offer services of implementation, management, customization and integration to the healthcare enterprises in Italy and abroad.

Challenges

- *The Open Three (O3) consortium project is collaboration between University of Trieste and University of Padova.*
- *Rooted from DPACS and MARiS*
- *Merge open source*
 - *Technologies*
 - *Clinical and technological standards*
 - *DICOM*
 - *HL7*
 - *Framework*
 - *IHE*
- *The mission is to promote an integrated three dimensions of the Health Policies.*
 - *Hospital*
 - *RHIOs*
 - *Home care*
- *Software is independent of platform, database, operating system, and languages*
- *Architecture is based on IHE actors.*
- *Workflow is based on IHE Integration Profiles.*
- *19 actors and 15 profiles implemented*
- *Participate IHE connectathon 2005 and 2006*

Industry Panel Pearls of Wisdom

Issues

- *PACS transition from silos into open systems/open source is about integrating heterogeneous architectural silos into a coherent homogeneous environment.*
- *Migration from legacy architecture into MCIM architecture/model costs tremendously to making the ultimate solution up front. An interim cost and clinically effective approach to implement needed changes required.*
- *Clinically, imaging modalities including dermatology, pathology, and oncology need to be addressed in consistent manner that radiology and cardiology are currently managed and protected.*
- *Meta-data must be registered and managed from the enterprise level to improve healthcare delivery process and efficiency across the continuum.*
- *Target should be towards “personalized medicine” rather than “median medicine” approach (where shotgun testing is done and then evaluated).*
- *Vendors must allow decoupling or fragmentation of their package so that customers will have greater flexibility. (Customer driven activity during the procurement process).*
- *Distributed health care model is needed rather than centralized, however there is some argument that both are needed in a balance for success.*
- *“Maria Gonzalez Syndrome” problem is solved with IHE, it just hasn’t been implemented. Need “scheduled Patient ID Reconciliation” implemented to automate the process.*

Challenges

- *Open source approach can reduce significant development time and costs by not having to build entire product from scratch, and/or purchase proprietary software.*
- *Open source collaboration is critical to distributed, cost effective development.*
- *Internet should be a model to “flatten healthcare” in terms of efficiency and quality (equates to cost, time to delivery, and enhanced quality).*
- *Education/marketing of clinical requirements, standards and related costs to the IT organizations is critical.*
- *There are barriers and gaps between end user and product development. “Listen to the customer”.*
 - *“Bottom up” via users’ groups*
 - *“Top down” from work with IHE and other professional groups*
 - *“Sideways across” via collaboration with distributed pool of open source developers (“Co-Laboratory”)*
- *There are difficulties with using the co-laboratory approach for development on live clinical systems. There must be parallel test and/or development systems in place to avoid disruption of clinical workflows/operations. Ideally, test systems should be used against the clinical data set*
- *Use Standards Organizations to guide development*

Next steps

- *Industry must be leveraged to build/implement IHE. The customers must drive this in their procurement instruments. However, must have a broader view of requirements to include smaller, more rural facilities/enterprises.*
- *Educate IT on Radiology/Clinical Requirements – Get into HIMSS*
- *Build IHE into procurement requirements in RFPs, - and be specific; - perhaps require conformance statements from manufacturers*

- *Look at previous efforts and other industries outside of medical for solutions; - e.g. pharmaceutical industry, banking industry to speed time to market and reduce costs for industry and customers.*

Mind the Gap!

Michael J. Ackerman, PhD, NLM/NIH

Issues

- *Significant barriers for open data and literature*
- *Concerns about the GAP between the grant and production filling because open software not free*
- *\$ over 4 years for development*
- *\$ year for sustaining*
 - *Future development cost*
 - *Distribution cost including acknowledgment of intellectual property issues*
 - *Help desk cost*
 - *Test costs*

Challenges

- Look at previous experiences with other successful open source (Apache, ITK, Linux, Biomed Central)

Next steps

- *Plan for becoming self sustaining should be part of the grant proposal or original plan*
- *Early adoption of a business model*
- *Diversification plan for open source projects*

Triple Helix Model

Conrad Clyburn. TATRC

The U.S. Army Medical Research and Materiel Command (USAMRMC), Telemedicine and Advanced Research Center (TATRC) is responsible for life cycle management of over 500 medical research and development programs, with a 2005 budget of approximately \$. The Center's research responsibilities extend to execution of academic, government and industry programs in telemedicine, medical informatics, advanced surgical technology and imaging, bioinformatics, medical modeling and simulation, biosurveillance, robotics, biomaterials, tissue engineering and nanotechnology. TATRC programs have produced a number of technologies that are in use by U.S. service members in the United States and overseas, by other federal agencies, and the White House medical unit. In addition, TATRC programs have generated hundreds of peer reviewed medical articles, scores of invention disclosures and patent filings, and dozens of patent licenses and spin off businesses. This presentation will review advanced imaging and Picture Archiving and Communications Systems (PACS) programs relevant to Multi-Center Image Management (MCIM), and how TATRC uses Triple Helix strategies involving academia, industry and government to accelerate technology implementation.

Issues

- *General inability to translate medical innovation to clinical use in federal as well as private sector*
- *Increased investment in medical research and development (JAMIA reported that medical research funding was doubled to \$ from 1994 to 2003)*
- *Best role for government is to spend its R&D money in early development stages to influence industry's future direction to meet government needs, reduce industry's technical risks and speed time to market*
- *Modifying commercial products to meet government needs can be expensive; locks in obsolescence and poor return on investment*

Challenges

- *Telemedicine and Advanced Medical Technology Program aims to apply physiological and medical knowledge, advanced diagnostics, simulations, and effector systems integrated with information and telecommunications for the purposes of enhancing operational and medical decision-making, improving medical training, and delivering medical treatment across all barriers.*
- *Projected FY05 funding is \$*
- *Core research leads to transformational technologies are directed energy, robotics, nanotechnology, immersive VR environments and biotechnology*
- *Typical TATRC Triple Helix Consortium is between academia, government and industry (Ex. BMIS-T, Chest Tube Simulator, Digital X-ray, Dreams Digital Ambulance, Smallpox Inoculation Training Unit, Medical Robotics, BRSS, STAT-Care and Retinal Imaging)*

An FDA Perspective

Alford Taylor, Jr., CDRH/FDA

Issues

- *CDRH mission is to protect and promote the public health by ensuring the safety and effectiveness of medical devices*
- *The regulatory reviewer's challenges are how well it need to work or how bad can it be and still be acceptable*

Challenges

- *Retrospective validation could be characterized as an augmented validation effort, incorporating all the checks and balances that would have been a part of a comprehensive design control process*
 - *Detailed requirements documents*
 - *Top-down and bottom-up risk analyses, risk evaluations, and risk control decisions*
 - *Comprehensive software/systems V&V*
 - *Clinical validation of the system*

NCI Resource for Assessment of Open Source Tools

Larry Clarke, PhD, NCI/NIH

Challenges

- *NCI caBIG Imaging Workspace is recently formed one that employs open source to:*
 - *Promote standards for image mark-up/annotation.*
 - *Encourage development of reference images and software standards for evaluation of software tools and data integration tools*
 - *Software for validation of imaging systems/platforms including simulation methods*
 - *Grant support through caBIG and NCI PAR's*
- *NCI research opportunities emphasis include an open source platforms and software tools*
 - *Reference image data bases required*
 - *Standardized methods for image annotation and mark up.*
 - *Objective and reproducible means to compare the performance of software tools*

Next steps

- *The early potential of open source tools may be the greatest for image annotation and other tools necessary for validation of imaging systems and methods.*
- *Open source tools that are application specific pose problems in terms of their assessment prior to use in clinical investigations*
- *FDA approval and CMS reimbursement may pose problems if non standardized methods for their performance are used.*

The United States Measurement System: Roadmapping America's Measurement Needs for a Stronger Innovation Infrastructure

Richard N. Spivack, PhD
NIST

Abstract

Critical diagnostic and clinical standards and techniques are required for the evaluation of medical images, medical imaging devices (includes both image acquisition devices such as digital cameras and microscopes, and display devices such as CRTs and LCDs), the evaluation of computer assisted diagnostic (CAD) tools, and the effects of compression on image quality. These evaluation processes are increasingly critical as new medical diagnostic and imaging techniques become available and as new or improved display technologies come into use. There is also a growing need to communicate and render image information across different information display systems. Diagnosticians in many areas have integrated new imaging devices into their practice, often without regard to fidelity issues that to too many are not particularly obvious. Thus, it has become routine, for example, for many doctors to take images home with them for viewing in the comfort of their homes. Images are routinely emailed to consulting physicians without regard to whether the displays on which they are viewed meet minimum performance standards. Images may be compressed for storage or for transportation across wireless systems. Incorrect rendering of a transmitted medical image could lead to an inaccurate diagnosis with potentially lethal consequences.

NIST explores the challenge and demands upon the U.S. Measurement System (USMS) by the new technologies and critical applications in medical imaging and telemedicine, and address how the USMS should be redefined to meet its role.

Issues

- FDA approval and CMS reimbursement may pose problems if non standardized methods for their performance are used.

Key features

- NIST builds partnership with the telemedicine community to enable high quality remote medical imaging through measurement practices and assurance procedures: and, facilitate standards development and interoperability while contributing to better health care quality.
- The U.S. Measurement System is the complex of all methods, instruments, entities, institutions, and standards involved in *measurements* of products and processes of significance to the economy, security, and quality of life of the Nation.
- NIST needs partnership with the public
- NIST have the expertise in multiple domains and can provide help in measurement
 - Define the template for data collection
 - Collect input
 - Conduct assessments
 - Create an action-plan roadmap
 - Report to customers and stakeholders on the state of the USMS
- Current measurement needs
 - Telemedicine Interoperability-Standards
 - TeleMental Health interactive video

- Coding for Tele-Mental Health and Surgical Endoscopy
- Telemedicine Digital Cameras
- Telemedicine Display Systems
- Telemedicine Imaging Systems
- Remote Image-based Medical Diagnostic Tools

Next steps

- NIST will focus its efforts in 3 areas:
 - BioChemistry
 - BioEngineering
 - BioInformatics

Peer to Peer Technology

Osman Ratib, MD, PhD, Universite de Geneve

With increasing requirements for wide access to images inside large distributed radiology departments as well as outside radiology departments in clinical services it has become difficult to provide adequate and efficient distribution of image data with traditional centralized architecture. We have elected to explore alternative solution based on peer-to-peer technology and grid architecture. The goal is being to allow users across the enterprise to access any study anytime without the need for pre-fetching or routing of images from central archive servers. Images can be accessed between different workstations or local storage nodes.

We implemented a new peer-to-peer and remote file access technology developed by Apple computer called "bonjour" that is imbedded in the latest UNIX-based OSX operating system version 10.4. Bonjour allows applications to share data and files remotely with optimized data access and data transfer. Our Open-source image display platform called OsiriX was adapted to allow sharing of local DICOM images through direct access of a local SQL database to be accessible from any other OsiriX workstation over the network. A server version of Osirix Core Data database also allows to access distributed archives servers in the same way.

The performance of peer-to-peer access to the images was found to be 10 to 20 x faster that accessing the same date from the central PACS archive. The convenience and high performance of the system allows multiple users to share data more efficiently and perform advanced image processing and analysis in a distributed environment. It is particularly suitable for large hospitals and academic environments where clinical conferences, interdisciplinary discussions and successive sessions of image processing are often part of complex workflow or patient management and decision making. Therefore we believe that peer-to-peer architecture connecting multiple workstations and temporary storage servers can provided an alternative system that can complement traditional PACS infrastructure and allow rapid and easy exchange of image data among large number of user and image processing workstations. (Antoine Rosset, Osman Ratib, Joris Heuberger)

Limitations of web-based image distribution

- *Slow*
- *Inefficient for large image sets*
- *No reformatting and 3D rendering*
- *Limited image processing*
- *Restrictive workflow*

Challenges

- *Peer-to-peer data sharing*
 - *Direct browsing of remote database*
 - *Direct access to image files on remote workstations*
 - *Use of Bonjour/TCP-IP protocol (zero configuration network protocol)*
 - *Optimized random image access*
 - *Simple graphic user interface for image retrieval across multiple workstations*
 - *Simple to use : Napster/ Kazaa model*
 - *Fast access*
 - *Open source*

Issues

- *Not HIPAA compliant & Security issues*
- *Platform dependant*
- *No IT support*
- *Hard to experiment in a production environment*

Recommendations

- *Use P2P as a testing application ex teaching files*
- *Can be used with anonymized data in research*
- *If successful, industry can take the application and make it a product*

Application Hosting: A Standardized API for Launching and Communicating with ‘Plug-in’ Applications

Lawrence Tarbox, PhD, Washington University at St. Louis

This presentation reports on the activities of DICOM WG 23. Many of the ideas were jointly developed by the participants in the WG, which includes representatives from GE, Philips, Kodak, Agfa, Siemens, Oracle, IBM, Mercury, Société Française de Radiologie, along with other representatives to the DICOM committee.

Motivation

- *The pace of research and clinical acceptance could be accelerated if analysis programs could be run in the clinical setting, as part of the clinical workflow, without time-consuming movements of people and data from WS to WS.*

Problem

- *Stakeholders in developing such agent-specific analysis applications typically are not the vendors/creators of the medical workstations*
- *Little market incentive for medical workstation vendors*
- *Stakeholders do not want to develop multiple versions of an application*

Proposed solutions

- *Create a mechanism where applications written by one party could be launched and run on systems created by multiple other parties*
- *Allow launched applications to efficiently access images and other resources controlled by the host*
- *Provide a framework for exchanging information about those applications*
- *Support both research and clinical environments*

Challenges

- *Goal of DICOM WG23 is to develop a standardized API that runs on any host that is:*
 - *Platform and language independent*
 - *Extensible*
 - *Secure*

Issues

- *Implementations of Open Standard Interfaces can be Open Source or proprietary*
- *Implementations on either side of the interface need not be created by the same entity*
- *Interoperability is gained by adherence to the standard*

HealthGrid: Grid Technologies for Biomedicine

Mary Kratz, University of Michigan

Use of GRID technologies to support effective healthcare information infrastructure is a component of national cyber infrastructure. GRID applications in biomedical environments enable the creation and operation of distributed communities across organizational boundaries. Enhanced collaboration environments, visualization tools, computational resources and storage capabilities are all GRID services upon which Virtual Organization can build information infrastructure. This emerging information technology infrastructure enables the creation, administration and management of image based biomedical information.

A HealthGRID is an environment where data of medical interest can be stored, processed and made easily available to the different healthcare participants: researchers, physicians, healthcare organizations, the public health sector, healthcare administration, individual citizens and other communities of practice. If such an infrastructure were to offer all necessary guarantees in terms of security, respect for ethics and observance of standard regulatory frameworks, it allows the association of post-genomic information and medical data. The possibilities open up new mechanisms to improve healthcare across a continuum of sectors.

There exists a common shared set of protocols that allows the construction of effective middleware software to deploy GRID services. A lack of clinical feedback has resulted in a lag of proven applicability, but a tipping point towards service-oriented architectures (SOA) is current underway. There is a need for clinical feedback to insure applicability and to address performance issues. Shared experiences provide an effective approach to collaborative partnerships in the interplay between medical and computer science expertise.

Challenges

- *From grid to HealthGrid:*
 - *Many current initiatives in Grid computing applied to healthcare at the national and international levels (EuroGrid)*
 - *Current efforts to develop standards*
 - *The value of virtual organizations to cross administrative boundaries*
 - *GRID benefits are possible TODAY for Biomedicine*
 - *GRID is foundation of good Cyber Infrastructure*
- *Bringing the HealthGrid*
 - *How to integrate little science into Big Science and globally.*
 - *Open Science*
 - *Globus Toolkit: Open Source Grid Infrastructure*

Next steps

- *HealthGrid requires a 'healthy' GRID*
 - *Strong algorithms*
 - *Functional OPEN architectures*
 - *Data sharing needs as part of a cultural shift*
- *Enable the 'incidental user'*
 - *How should a legislator find scientific basis before making a decision*
- *Address access policies*
 - *Storage Request Broker (SRB)*
 - *Creative Commons*
- *Real-time simulations and test beds are needed*
 - *Human capacity building*

Network Security for Medical Devices & Systems Conference

Arlington Hilton Hotel
Arlington, Virginia
June 12-14, 2006

Abstracts

Cyber-security in Medical Devices, Problems and related Guidance; - FDA Perspective **Brian Fitzgerald, Deputy Director, Electric Engineering and Software, FDA**

FDA has published guidance to industry relating to the modification and update of certain aspects of computer controlled medical devices. These devices are routinely subjected to threats related to unauthorized intrusion, malware and the like. These threats can only be mitigated by measures implemented within a close relationship between the COTS vendors the device manufacturer and the device user, which protect the regulatory landscape of each member. A brief discussion of the problem and the guidance will be presented.

Cyber-security in Medical Devices; - Industry Perspective **Evan Gaddis, President and CEO, NEMA** **Jess Edwards of Eastman Kodak**

In an effort to deliver the highest value technology at the lowest price, the medical device industry has increasingly built their solutions with commercial off-the-shelf software. At the same time, the healthcare industry has realized significant cost savings by improving workflow and providing caregiver access to just-in-time information near the point of care. Information Technology and engineering staff now interconnect many IT-based hospital devices – putting large-scale enterprise systems on the same network with laboratory, monitoring, diagnostic, and treatment systems. The past three years have seen an unprecedented rise in malicious computer attacks via network. Although these have not generally targeted healthcare, hospital systems have experienced the downside of being collateral victims in cybersecurity attacks. Because of their position as high-value targets for terror-inspired attacks, military healthcare organizations are tightening security and restricting vendor access for local and remote servicing. This has created some tensions as manufacturers work to assure continuity of equipment operation while working out how to meet these sometimes locally interpreted requirements (e.g., security access, background investigations, etc.). This presentation provides a broad view of what the medical device industry is doing collaboratively with healthcare providers to mitigate and manage these risks. It identifies the most active groups working on the issues around security and privacy in medical devices and details some of the sticking points when the “rules of engagement” change unilaterally – as when the DoD/VA issue new security requirements for hospital access and device features.

Cyber-security and Medical Devices; - Changing the Manufacturer Organization

Nick Mankovich, PhD, Philips Medical Systems

This presentation goes beyond broad industry efforts to show what a typical NEMA-member company is doing to ensure the confidentiality, integrity, and availability of these mission-critical and life-critical devices, including improvements in product creation, organizational changes, and enhanced customer technical security communication. The medical device manufacturers are changing to provide for security risk management throughout the product life cycle, including new security requirements, vulnerability monitoring, incident response, and high-speed security patch validation – all under the strict framework provided by government regulations. In short, I present what medical device manufacturers are doing, discuss some of the constraints, and ask the conference attendees, “What can we do better while maintaining safe, effective, and cost-efficient healthcare?”

Medical Device Security; - US Air Force Perspective

Sean Murphy, Major, US Air Force Medical Logistics Office

Medical Device Security from an AF Perspective Where “One Air Force, One Network” meets “Any Image, Any Where, Any Time” is the focus of this brief. The various security requirements put in place to protect the warfighter’s network have tremendous impact on developing an interconnected medical community of interest. Other DoD Services and government agencies (e.g. VA) have addressed security in seemingly individual ways. It is difficult to convince medical device manufacturers and vendors the “rules” have their origin in the same regulations. The diversity in interpretation and enforcement varies greatly and is confusing. Opportunities begin in dispelling the myths around Air Force’s interpretation and enforcement of DITSCAP, NAC, and IA regulations (as opposed to others in DoD).. Further, exploring the Air Force Medical Service’s vision for a digital imaging grid is key to a common understanding of the way forward. From the vendor perspective, an understanding of the Air Force medical device security perspective will foster a tangible competitive advantage (within DoD and private sector). Along with DoD MTF’s, civilian hospitals/health systems are increasingly security-focused as SOX, HIPAA, and numerous state and federal privacy/security requirements carry financial ramifications to their bottom lines.

DoD Information Assurance Policy in Support of Bio-Medical Networks and System Security; - The Network-Centric vision. – From the medical domain, looking for feedback for improvement as a result of this conference.

Glenda Turner, Office of the Assistant Secretary of Defense (Networks and Information Integration)

The Department’s Network-Centric vision is one of an agile, robust, interoperable and collaborative environment, where warfighters, business, and intelligence users all share knowledge in a secure, dependable and global network that enables informed decision-making, effective operations, and network-centric transformation. As we transition from a system-centric to a network-centric environment, it is essential that appropriate Information Assurance (IA) measures be incorporated to insure that DoD systems, networks and information are protected. The Department has a resilient IA policy framework that provides overarching IA guidance for protecting information, systems, and networks. This

presentation will highlight key IA policy and guidance, and solicit feedback from the conference attendees regarding possible problems, misapplication or misinterpretation of policy, and recommendations for improvement, focusing on the medical domain.

2006 Information Assurance (IA) Workshop – Dynamic IA for the Global Information Grid (GIG): Securing the Warfighter Today and Tomorrow

Jennifer Ellett, TRICARE Management Activity (TMA), Office of the Assistant Secretary of Defense

Discussion of the 2006 IA workshop - Dynamic IA for the GIG: Securing the Warfighter Today and Tomorrow - All about Execution. Discussion of the JMIS works to adapt to the changing IA requirements for operating on the DoD network.

Building Protected Networks for Clinical Systems; - Military Health System Perspective, Lessons Learned and Focus for the Future

Phillip LaJoie, Tri-Service Infrastructure Management Program Office (TIMPO), Military Health System (MHS)

Discussion of building protected networks for clinical systems on government networks from an MHS perspective. Lessons learned and focus for the future.

Army Security Architecture for Medical (ARSAM)

Steven Foote, Senior Engineer, Program Executive Office, Enterprise Information Systems Technology Applications Office

The Army Security Architecture for Medical (ARSAM) provides a framework to use to implement a Defense-in-Depth network security architecture by incorporating information assurance and security as an integral component through the use of private IP addressing, protected/isolated Virtual Local Area Networks (VLANs), Access Control Lists (ACLs), intrusion detection, firewalls, and internal device security. It is envisioned that a “Deny All, Permit by Exception” security policy will be applied to the ARSAM and the Medical Treatment Facility enterprise data network, and that only traffic required to maintain and improve current patient care capabilities will be permitted to access to the protected medical device VLAN. This strategic approach and the network configuration measures associated with its implementation will serve to mitigate the risk of networking medical devices/systems, and buy time for medical device manufacturers to test and validate required vulnerability patches and as a best business practice.

Proxy Servers and Secure Communications for Clinical Workflows

Matt Ketko, Agfa Healthcare Security Engineer

This discussion will focus on the use of proxy servers for communications of various standard protocols typically in use (DICOM, HL7 and HTTP/S). In an environment that is seeing ever increasing sharing of patient data, radiologist resources, and archiving capabilities, a tremendous effort must be made to ensure these external connections are secure. Sites vary in their equipment as well as vendor architecture. To presume that a site's IM/IT department will allow all the external connections that are required can mean upwards of 20 or more connections through the firewall. Every opening represents a risk and so the fewer the better. Proxying these types of connections may help to tighten

perimeter security by closing as many openings as possible and still allowing the site to fully integrate with external sites.

Veterans Administration (VA) Medical Network Isolation Architecture

Steven Wexler, Veterans Administration

VA Isolation Architecture Increasingly, medical devices are designed using commercial operating systems and other software providing better function through user familiar screens and with the added capability to be networked to facility information technology networks. There are many benefits when medical devices are networked including ready availability of data and images from diagnostic exams to clinical staff nearly as soon as they are released thereby providing for more effective care. But the increasing use of networked technology also exposes critical hospital equipment to risk from attack by a software worm, virus, or other software security breach. Because medical devices are designed for a specific, special purpose with particular design considerations and constraints, we cannot presently take the same approach to protecting medical devices from software vulnerabilities that are used with other, more general purpose IT devices. Examples include routine patching of commercial operating systems in medical devices or application of anti-virus software to medical devices. Such actions can potentially change the operating function of the medical device with the possibility for negative impact on patient safety and, therefore, cannot be undertaken by the end user without the expressed support and consent of the original equipment manufacturer. The isolation architecture described in the Department of Veterans Affairs Medical Device Isolation Architecture Guide, aka the Virtual LAN or VLAN, addresses risks associated with medical devices connected to facility information networks without impacting the operational characteristics of the devices.

Security Architecture for Radiology Picture Archive and Communications System (PACS) in the Great Plains Regional Medical Command (GPRMC)

Gary Crouch, Director of Telehealth, GPRMC

This session will describe the overall security architecture for radiology Picture Archiving and Communications Systems (PACS) in the Great Plains Regional Medical Command. Explore practical procedures and methods used protect PACS and the associated medical devices to ensure continuity of operation.

Overview of Global Interconnectivity of the Healthcare Community, the Internet, and DoD

LeRoy Luginbill, Strategic Command, Joint Task Force – Global Network Operations

The Department's Network-Centric vision is one of an agile, robust, interoperable and collaborative environment, where warfighter, business, and intelligence users all share knowledge in a secure, dependable and global network that enables informed decision-making, effective operations, and network-centric transformation. As we transition from a system-centric to a network-centric environment, it is essential that appropriate Information Assurance (IA) measures be incorporated to insure that DoD systems, networks and information are protected. The Department has a resilient IA policy framework that provides overarching IA guidance for protecting information, systems, and networks. This presentation will highlight key IA policy and guidance, and solicit feedback from

*the conference attendees regarding possible problems, misapplication or
misinterpretation of policy, and recommendations for improvement, focusing on
the medical domain*

Appendix C

Publications

Open Source Software for Multi-center Image Management: ImTK™ Consortium

Seong K. Mun, Member, IEEE, Mary Lou Ingeholm, Walid Tohme
and Kevin Cleary, Member, IEEE

Abstract— Development of software through an open source approach has gained popularity in the information technology (IT) community. Open source software coupled with open architecture is seen as a critical component to promoting open science. Furthermore US government agencies are promoting an open source approach as a means to transfer research software technology to greater commercial applications. Successful open source efforts require a number of key elements such as free licensing, presence of active participants and an engineering discipline that will generate robust high quality software with necessary documentation. It also requires an innovative business model since the code itself is made available freely. In healthcare specifically, the role that FDA plays in software engineering must also be addressed. Recently, a workshop was organized to review the role of open source in the area of healthcare informatics. The IT capabilities in healthcare are maturing rapidly for many types of patient care settings yet there is a significant gap in the ability to share biomedical data in multi-center applications and research. A new consortium is being launched to promote the development of software tools for information and image exchanges in the multi-center environment using an open source/open architecture approach.

INTRODUCTION

In March 2006, the Multi-center Image Management (MCIM) Workshop explored open source strategies in support of flexible access to biomedical data for the research community. The group recognized the technology gaps between commercial information systems that focus on efficient clinical operations within a single institution and the research environment which requires flexible access to multimedia data generated by different vendor products and residing in multiple distributed repositories. It was further noted that these gaps are not likely be addressed by the commercial community any time soon as the market for such capability in the current biomedical environment is very limited. The workshop participants concurred that open source, open standards, and open architecture can be efficient methods of supporting open science and improved interoperability. Examples of robust open source projects and software methodologies were presented and there was broad agreement that adequate rigor must be incorporated into an open source process in order to meet the highest standards of software quality. Several examples of successful business models for maintaining the development effort were described and the importance of long term sustainability beyond initial government funding was discussed. An open source approach was also introduced as a new model for collaboration between academia, industry and government. The workshop concluded that an open source effort by the research community to develop robust, freely available tools that meet the information management needs of basic, clinical and translational research is essential to mend the gap between the research and clinical communities [1].

PROBLEMS TO BE ADDRESSED

The information requirements for a biomedical research environment are markedly different from the clinical environment. Commercial medical information and imaging systems are designed to support efficient clinical operations within a single organization whereas researchers need to be able to integrate research data with clinical data often

residing in multiple distributed information repositories. The information management components for research must be able to handle more complex queries, data mining and a broad spectrum of data types beyond routine clinical data [1]. This gap between clinical and research requirements prevents the efficient exchange, sharing, management, and analysis of multimedia medical information such as clinical information, images, and bioinformatics data as well as proteomics data sets, significantly impacting the capability to translate research into clinical outcomes. Thus, while hospitals and research communities are collecting unprecedented amounts of clinical data and research data, the ability to data mine these rich collections to support research is limited within an institution and is essentially nonexistent across institutions. Bioinformatics and proteomics data have become increasingly important in clinical research but there are not efficient ways to incorporate these data with clinical information. Multi-center clinical trials are common activities yet many of the trials are still managed manually and cannot optimize the value that a multi-center model represents. Each of these issues is a direct result of the inability to exchange multimedia clinical data and research information across different organizations and functional environments and impedes the ultimate goal of improving patient outcomes.

The current situation calls for innovative solutions that engage a broad community of users. Using an open source and open architecture framework would allow rapid implementation of scalable and robust software development in a cost effective manner by a community of users from academia, industry and government.

AN OPEN SOLUTION: OPEN SOURCE SOFTWARE DEVELOPMENT

Adopting an approach that includes open source software and an open architecture is essential to a solution that can bridge the information management gap between functional environments within an institution and across multiple institutions. An open source framework supports rapid software development while open architecture encourages interoperability across different environments. An open methodology for this effort will encourage development and implementation of software applications that can expedite translational research in a multi-center setting.

Open source software development has become a cultural as well as an economic phenomenon within the information technology (IT) community. It efficiently harnesses global skills and resources, resulting in accelerated research and development. Open source initiatives encourage high level technical communication, provide conventions for interoperable software development, establish a baseline for improvement, open the field to “beginners”, and create common ground for product development [2]. There is also a growing body of evidence that open source software produces more robust code with fewer bugs. From a government perspective, the demand for open access for taxpayer-funded projects and the need for quality and performance in mission critical applications is leading to an increased demand for open source solutions [3]. Within the National Institutes of Health (NIH) specifically, the requirements for accelerating discovery include promoting team science, lowering barriers and entry costs, enabling (enforcing) repeatable results and eliminating oversight through transparency. An open source software tactic reduces redundancy of research, enforces good research practices, and

enables sharing of ideas [2]. Overall, the open source software concept has the greatest potential for success in developing tools that can bridge the clinical information management gap between the research and clinical communities.

AN OPEN SOLUTION IN BIOMEDICAL APPLICATIONS

There has been remarkable penetration of open source software in medical imaging research software. The Visualization Toolkit (VTK) [4] and the Insight Toolkit (ITK) [5], supported by the National Library of Medicine (NLM) of the NIH represent two large, mature, and globally utilized open source toolkits that provide state-of-the-art imaging architectures and algorithms to application developers. VTK provides a wide range of advanced multi-dimensional visualization algorithms including volumetric reformat, volume rendering, and geometric surface rendering algorithms. ITK provides advanced image processing algorithms, with a particular emphasis on medical image segmentation and image registration algorithms. VTK and ITK were developed with a strong emphasis on advanced computing technologies and software quality. The C++ software architecture of these toolkits has evolved over the years to support a wide range of advanced algorithms and computing technologies including parallel computing. In addition, several computational tools and utilities have been developed that facilitate the global development of a high quality toolkit including a cross-platform build tool called CMake and a software quality dashboard called DART. These open source imaging toolkits, and their supporting tools and utilities, represent a large and growing resource for future open source technology solutions [6].

The Image-Guided Surgery Toolkit (IGSTK) [7], another project supported by National Institute of Biomedical Imaging and Bioengineering at the NIH, is an open source, cross platform, software toolkit. IGSTK integrates the basic components needed in surgical guidance applications and provides a common platform for fast prototyping and development of robust image-guided applications [8].

In recent years, open source software has gained visibility in the healthcare community. Several lead projects include OpenVista, a patient information system based on the Veteran Administration's system, Care2X, an integrated practice management solution in Europe and Health Infoway, a patient data-exchange venture in Canada [9].

REQUIREMENTS FOR A SUCCESSFUL OPEN SOURCE SOFTWARE FRAMEWORK

While a successful open source software effort can produce rapid, innovative and cost-effective software development, making it successful requires not only an understanding of the technical and business requirements of an open source software framework but the cultivation of a community of users who can contribute and benefit from the endeavor.

Open architecture requirements

An open source software approach must be coupled with an open architecture to be sustainable in the long run. "Open" refers to the process used to develop standards that achieve interoperability where "architecture" defines the components, their organizations and interactions, and the design philosophy used [10]. Standardization is critical for creating interoperable, portable, and reusable components and systems; it also contributes to the development of secure, robust, and scalable systems. Grid technologies have

emerged as a component of the national cyber infrastructure supporting effective healthcare information. The underlying open grid services architecture (OGSA) represents a growing trend in systems architecture. The key to the realization of this Grid vision is standardization, so that the diverse components that make up a modern computing environment can be discovered, accessed, allocated, monitored, accounted for, billed for, etc..., and in general managed as a single virtual system—even when provided by different vendors and/or operated by different organizations [11].

Grid applications in biomedical environments enable the creation and operation of distributed communities across organizational boundaries. Enhanced collaboration environments, visualization tools, computational resources and storage capabilities are all grid services upon which Virtual Organizations can build information infrastructure. This emerging IT infrastructure enables the creation, administration and management of image based biomedical information. [12]

Technical Requirements for an Open Source Software framework

Open-source evangelist Eric S. Raymond suggests a model for developing open source software known as the Bazaar model. He advocates that all software should be developed using the bazaar style, described as "a great babbling bazaar of differing agendas and approaches" [13]. In order to make this model effective, Gregorio Robles suggests the following principles [14]: (1) Users should be given access to the source code of the software and be encouraged to submit additions, code fixes, bug reports, documentation etc.... Having more co-developers increases the rate at which the software evolves. (2) The first version of the software should be released as early as possible so as to increase one's chances of finding co-developers early. (3) New code should be integrated as often as possible so as to avoid the overhead of fixing a large number of bugs at the end of the project life cycle. (4) There should be at least two versions of the software - a development version with more features and a more stable version with fewer features. The development version is for users who want the immediate use of the latest features, and are willing to accept the risk of using code that is not yet thoroughly tested. The users can then act as co-developers. The stable version offers the users fewer bugs but fewer features. (5) The general structure of the software should be modular allowing for parallel development. (6) There is a need for a decision making structure, whether formal or informal, that makes strategic decisions depending on changing user requirements and other factors.

Distribution Scheme for a Successful Open Source Software framework

As with proprietary software, open source software is distributed under a license. To help establish some degree of uniformity, the Open Source Initiative (OSI) created the Open Source Definition which is a specification of what must and must not appear in a license in order for the software to be considered open source. To meet the open source definition, a license must provide the following features [15]: (1) The license shall not restrict any party from selling or giving away the software as a component of an aggregate software distribution containing programs from several different sources. (2) The program must include source code, and must allow distribution in source code as well as compiled form. (3) The license must allow modifications and derived works, and must allow them to be distributed under the same terms as the license of the original

software. (4) The license must not discriminate against any person or group of persons. (5) The license must not restrict anyone from making use of the program in a specific field of endeavor. For example, it may not restrict the program from being used in a business, or from being used for genetic research.

SUSTAINABILITY AND BUSINESS MODELS

Although an open source software framework is cost effective, it is not free. There are costs associated with the process. To maintain and grow the effort requires a sustainability plan that goes beyond the initial funding period. Money will not come in through traditional licensing fees, thus other business models need to be considered. As open source software development has matured, a number of business models for sustainability have emerged.

In the service/maintenance model companies sell support and services around the open source software, for example, Red Hat (Linux) or Medsphere (OpenVista). In this approach, users pay for support of the software although they may choose to support the software themselves. In another approach, the vendor provides an open source code base with proprietary add-ons. Examples of this model include Sourcefire (security) and SugarCRM (customer relationship mgt). In a dual license approach, a company offers free use of its software with some limitations, or alternatively offers commercial distribution rights and a larger set of features for a fee. Both the MySQL and Sleepycat databases are examples of a dual license model. In the Aggregation Model also known as the “Lego” strategy, companies act as middlemen to assemble various open source packages into easy-to-use integrated units. SourceLabs and SpikeSource have adopted this model [9].

NEW BUSINESS MODELS FOR ACADEMIA, INDUSTRY AND GOVERNMENT

The NLM has been one of the champions of open source software development. As the imaging data from the Visible Human Project were released for public use, the NLM set out to “create a dynamic, self-sustaining, public domain and extensible toolkit that will empower researchers throughout the world to develop new segmentation and registration algorithms and create new applications that leverage the NLM’s investment in the Visible Human Male and Female data sets” [16]. The project produced the Insight Tool Kit after four years and seven million dollars of government funding. This experience made it clear to the government that while open source developed by government grants may promote open science and empower researchers, it is not free. There are costs associated with the effort such as distribution of the software, quality control of the software, and user support. In order to cross the “valley of death” between research and successful technology transfer, it is imperative that an open source effort can be converted to a financially sustaining activity.

An open source software approach offers a unique way for academia, industry, and government to work in partnership to facilitate rapid dissemination of knowledge into the commercial sector for wider applications. Software developed by the academic research community, under government sponsorship can be offered to the open source community for further testing and development and eventual adoption by the commercial industry.

The US Army Medical Research and Materiel Command (USAMRMC), Telemedicine and Advanced Research Center (TATRC) is responsible for life cycle management of over 500 medical research and development programs, with a 2005 budget of approximately \$300 million. The Center's research responsibilities extend to execution of academic, government and industry programs in biomedical research. TATRC is currently developing a program to improve the productivity in technology transfer from research community to the commercial sector. This program uses Triple Helix strategies involving academia, industry and government to accelerate technology implementation. The open source approach is seen as a potentially effective means of making research results available for greater dissemination through timely commercialization [17].

ESTABLISHMENT OF A CONSORTIUM: ImTK™

A new consortium has been formed to launch an open source/open architecture effort that narrows the gap between clinical and research needs by focusing on the development of software tools that enable the efficient exchange, sharing, management, and analysis of multimedia medical information. Imaging and informatics experts at Georgetown University, Washington University in St. Louis, the Northwestern University Feinberg School of Medicine and University of Geneva, Switzerland have agreed to form the Image Management Toolkit (ImTK) Consortium. Collectively this consortium represents demonstrated expertise in technology, clinical operations, technology development, and technology management within the academic, government and industrial environment.

The mission of the ImTK™ Consortium is to expedite translational biomedical research through the development of software tools that enable efficient exchanging, sharing, management, and analysis of multimedia medical information such as clinical information, images, and bioinformatics data. The ImTK™ Consortium, together with partners in academia, industry and government, will organize itself around four cores: 1) software tool development, 2) open architecture and data model implementation, 3) knowledge dissemination, and 4) management and sustainability. A well managed open source development process has been proven to produce high quality products in a cost efficient manner while simultaneously developing a collaborative user/developer community. The ImTK™ technology initiative will not only provide open source software tools and components but also an open architecture in which they may be configured and deployed. The tools will comply with existing standards such as Digital Imaging and Communications in Medicine (DICOM) and Health Level Seven (HL7) and build on the technical frameworks and workflow defined by the Integrating the Healthcare Enterprise (IHE) initiative. The open architecture will draw on the best practices of the grid computing community and service oriented architecture. This new effort will build on the expertise, processes and development tools used to create ITK and VTK. It will also bring insight and definition to the role the FDA will play in regulating open source efforts in the healthcare arena [17]. These processes will ensure the robustness of the software and extend the family of toolkits from image analysis and visualization to multimedia information management, information fusion and data mining.

The consortium will start by developing a collaborative environment for a community

of developers and users to work together to define use cases and application scenarios, design and develop new tools and components, and maintain a test bed on which components may be validated and training programs developed and conducted. It will draw on existing successful programs and activities for best practices and insights. The goal is to establish a dynamic, self-sustaining, public domain and extensible toolkit that empowers scientists, engineers and physicians throughout the world to improve the outcome of biomedical research and leverage the government's investment in open source initiatives. The consortium will support the development of robust software for research applications and commercial products through conferences, training sessions, and tutorials.

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